



Denise M
Sofranko/NM/APHIS/USDA
11/02/2010 06:27 PM

To Barbara A Kohn/MD/APHIS/USDA, Nora E
Wineland/CO/APHIS/USDA@USDA
cc
bcc

Subject Fw: Letter to USAHA subcommittee on tuberculosis in
elephants of the Tuberculosis Committee

Janet just sent this to me. Interesting group of names on the letter. We can discuss tomorrow on the call but we can use some of this as basis of our talking points and ppt. for USAHA presentation.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

----- Forwarded by Denise M Sofranko/NM/APHIS/USDA on 11/02/2010 04:25 PM -----



Janet B
Payeur/IA/APHIS/USDA
11/02/2010 03:19 PM

To Denise M Sofranko@aphis.usda.gov
cc

Subject Fw: Letter to USAHA subcommittee on tuberculosis in
elephants of the Tuberculosis Committee

fyi - too bad we won't be at USAHA this year. Do you know any of the other vets who signed the letter?

Janet B. Payeur DVM, MPH, PhD
Scientific Outreach Coordinator
National Veterinary Services Laboratories
1920 Dayton Avenue
Ames, IA 50010

515-337-7003
Fax 515-337-7397

E-mail: Janet.B.Payeur@aphis.usda.gov

----- Forwarded by Janet B Payeur/IA/APHIS/USDA on 11/02/2010 04:17 PM -----

(b)(6)
(b)(6) @aiainc.com>

To "Janet.B.Payeur@aphis.usda.gov" <Janet.B.Payeur@aphis.usda.gov>
cc (b)(6) @msn.com" (b)(6) @msn.com>, (b)(6) @embarqmail.com"
(b)(6) @embarqmail.com> (b)(6) @palmbeachzoo.org" (b)(6) @palmbeachzoo.org>

11/02/2010 02:09 PM

Subje Letter to USAHA subcommittee on tuberculosis in elephants of the Tuberculosis Committee
ct

Janet,

Attached is a letter with signatures from several veterinarians including myself that care for elephants in zoo and private facilities throughout the U.S. There were a couple of other veterinarians ,whom plan to write their own letters and forward to you in the near future. It is our wish that a measured scientific approach will be utilized in

evaluating the current guidelines before additional guidelines are considered.

Thanks for your consideration of this matter. See you Minneapolis.

(b)(6)

Director of Research and Conservation

<http://www.elephantcenter.com>

[attachment "USAHA letter.pdf" deleted by Barbara A Kohn/MD/APHIS/USDA]

October 28, 2010

Janet Payuer, Chair
USAHA Subcommittee Tb in Elephants
Scientific Outreach Coordinator
National Veterinary Services Laboratories
1920 Dayton Avenue
Ames, IA 50010

Dr. Payuer,

As practicing veterinarians at various elephant handling facilities throughout the United States, we wanted to express our concerns regarding the consideration for changing the recently initiated "Guidelines for Control of Elephant Tuberculosis" by the USAHA to be recommended to USDA-APHIS, Animal Care.

The current guidelines have been in place less than seven months and about half of elephant population in the U.S. have been tested under the new guidelines. There have been ongoing concerns expressed for the challenges seen with the current guidelines, and our foremost concern is for the health of the elephants in our care.

The adoption of the current guidelines were developed primarily by an ad hoc group of scientists, veterinarians, and advisors over a period of several years. Those guidelines were still under discussion by the ad hoc group (primarily regarding treatment issues) but were brought before the USAHA Tuberculosis committee in an effort to further the transparency and science in addressing this issue. While we agree with the need to update and review the science and adjust the "Elephant TB Guidelines" as new information becomes available, we do not believe that sufficient evidence regarding the ancillary testing using the Elephant STAT-PAK and MAPIA testing by Chem-Bio is sufficient to warrant the changes being put forward by your committee.

One area of concern is the continued lack of acknowledgement that current treatment regimens, recommended in the current "Guidelines" have caused serious and sometimes fatal health issues in the animals meant to be cured. We are also concerned with what we see as an attempt by USDA/APHIS to use the recently adopted STAT-PAK and MAPIA assays to trigger treatment, regardless of the risks of false positives. At present, STAT-PAK and MAPIA tests are recommended as ancillary (screening) tests and they should not be mandated to make decisions regarding veterinary care. The intrusion of USDA, APHIS-Animal Care into the decision process for mandating treatment regimes for any disease is unprecedented in any species. With a species as highly endangered as the elephant, we must not take the risk of losing even a single individual based on a yet to be validated test. The recent death of an elephant following treatment for TB, based on the Elephant STAT-PAK/MAPIA tests and not the "gold standard" for tuberculosis gives us pause for concern.

A second area of concern is the consideration of changing the guidelines is to impose restrictions on the travel of elephants whom are Elephant STAT-PAK reactive. We agree that the test may have some value to determine exposure, and increased risk of having either latent or active tuberculosis, it does not rise to the level of determining that elephants should not be able to travel. The current guidelines have not been implemented but a few months and the value increasing the number of trunk washes evaluated for detecting those elephants that have active tuberculosis has not been evaluated. We would encourage the committee use due diligence in evaluating the science available and balance the health of the elephants that will be negatively affected by unnecessary treatment. The utilization of increased trunk washes is based on information collected in the past 12 years by our elephant facilities and recommended by the Ad Hoc TB Task Force to the USAHA in 2008. We would urge the committee to leave this recommendation as is.

We would appreciate the committee efforts to clarify several areas of the current guidelines. These would include defining what constitutes exposure. This is a difficult but essential element of the guidelines that need clarification. In addition the guidelines do not clearly define into which classification that a STAT-PAK reactive and MAPIA negative elephant should be placed.

We wish to encourage the tuberculosis in elephants sub-committee of the USAHA Tuberculosis Committee to incorporate the expertise of several previous members of the Ad Hoc Tuberculosis in Elephants Task Force as well as other experts in their consideration of future recommendations to USDA, APHIS-Animal Care.

Thank you for your consideration of our concerns. We have a great deal of expertise and knowledge to bring to the discussion and hope that we can work cooperatively to ensure the future of elephants.

Sincerely,

The undersigned Veterinarians

cc: (b)(6) Chair USAHA Tuberculosis Committee)

Sincerely,

The undersigned Veterinarians

(b)(6)





Denise M
Sofranko/NM/APHIS/USDA
09/14/2010 02:05 PM

To Barbara A Kohn/MD/APHIS/USDA
cc
bcc
Subject Fw: TB in elephant subcommittee for USAHA

fyi

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

----- Forwarded by Denise M Sofranko/NM/APHIS/USDA on 09/14/2010 12:05 PM -----



Janet B
Payeur/IA/APHIS/USDA
09/09/2010 04:41 PM

To (b)(6)@feldinc.com>
cc (b)(6)@msn.com", (b)(6)
@msn.com>, (b)(6)
(b)(6)@eldinc.com>
Subject RE: TB in elephant subcommittee for USAHA

The subcommittee is made up of myself (b)(6) Ray Waters, Chuck Massengill, and (b)(6) I believe that (b)(6) was trying to get a mix of people with elephant and TB experience and keep it relatively small so that it would be more workable. If you have Stat Pak or treatment data that you would like to share with the subcommittee, it would be much appreciated as we look at different interpretation scenarios.

Janet B. Payeur DVM, MPH, PhD
Scientific Outreach Coordinator
National Veterinary Services Laboratories
1920 Dayton Avenue
Ames, IA 50010

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E-mail: Janet.B.Payeur@aphis.usda.gov

(b)(6)
(b)(6)@feldinc.com>

09/09/2010 04:54 PM

To "Janet.B.Payeur@aphis.usda.gov" <Janet.B.Payeur@aphis.usda.gov>
cc (b)(6)@msn.com", (b)(6)@msn.com>, (b)(6)
(b)(6)@feldinc.com>
Subje RE: TB in elephant subcommittee for USAHA
ct

Janet,

I have several questions regarding the committee composition. Were members and or experts whom had been a part of the formulation of the original guidelines a part of this committee/discussion? How can I become a member of this subcommittee, and participate in the ongoing discussions? What data has been generated, or information that would drive a discussion for changing the current guidelines (which have only been implemented for six months)?

(b)(6)

Director of Research and Conservation

<http://www.elephantcenter.com>

From: Janet.B.Payeur@aphis.usda.gov [mailto:Janet.B.Payeur@aphis.usda.gov]

Sent: Thursday, September 09, 2010 5:42 PM

To: (b)(6)

Cc: (b)(6)@msn.com; (b)(6)

Subject: Re: TB in elephant subcommittee for USAHA

(b)(6)

An elephant TB subcommittee was formed during the 2007 USAHA TB committee b (b)(6) and is only active if there are issues that have been brought forth. The subcommittee revised the Elephant TB guidelines in 2008 and have been asked to look at them again this year for possible updates. Right now, I do not know if we will actually meet at USAHA in a separate meeting. We are conducting multiple conference calls right now and hope to have recommendations for the TB committee by the Nov. 2010 meeting. If you have some concerns or suggestions to the 2008 guidelines, please let me know and we will try and address them before the meeting. Janet

Janet B. Payeur DVM, MPH, PhD
Scientific Outreach Coordinator
National Veterinary Services Laboratories
1920 Dayton Avenue
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515-337-7003
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E-mail: Janet.B.Payeur@aphis.usda.gov

(b)(6)

(b)(6)@feldinc.com>

To "Janet.B.Payeur@aphis.usda.gov" <Janet.B.Payeur@aphis.usda.gov>

cc (b)(6)@msn.com" (b)(6)@msn.com>, (b)(6)

(b)(6)@feldinc.com>

09/09/2010 04:12 PM

Subje TB in elephant subcommittee for USAHA
ct

Janet,

While I can find no reference to a Tb in elephants subcommittee of USAHA, I have been informed that you are the chairman of this subcommittee. I am interested in whether there would be the opportunity to attend, and speak with this subcommittee during the USAHA meeting. I have been attending the USAHA annual meeting for the past few years, and active on several committees. However, this is the first I have heard of an elephant Tb subcommittee for USAHA. This concerns me since, I was on the original TB working group and have been very active for over 25 years in elephant medical care.

Thanks for your reply.

(b)(6)

A large rectangular area of the document is redacted with a solid grey fill, obscuring the text underneath.

<http://www.elephantcenter.com>



Denise M
Sofranko/NM/APHIS/USDA
06/22/2010 05:23 PM

To Janet B Payeur/IA/APHIS/USDA
cc Barbara A Kohn/MD/APHIS/USDA@USDA,
(b)(6)@embarqmail.com, Denise M
Sofranko@aphis.usda.gov, (b)(6)
bcc
Subject Re: elephant TB conference call

Hi all,

I'm looking forward to the call tomorrow and appreciate all of you taking the time for a discussion.

I've taken the test results that we have so far and removed identification and location. We are about a third of the way done with the testing.

I had hoped to have MAPIA results for another group for tomorrow's call but we only have some partial results for that. I'll explain tomorrow.

I've attached the spreadsheet and will help you make more sense of it tomorrow. I will also have the full spreadsheet for the call so can answer specific questions about some of the cases without revealing too much. We need to keep this very confidential at this point.

I'm also including some language from an e-mail that (b)(6) from Florida wanted to have you address. You can tell there is some frustration on the part of him and some other folks in regulatory positions.

From (b)(6)

Thanks for talking with us yesterday and discussing the October 2008 , Guidelines for the Control of Tuberculosis in Elephants 2008. I am hoping the USAHA subcommittee for elephant tuberculosis does review our concerns and makes modifications of their recommendations based on their scientific knowledge and expertise.

We have the following concerns:

The guidelines appear particularly inconsistent with respect to Stat-Pak MAPIA positive animals that are not culture positive. According to the guidelines, these animals "should be considered at increased risk" and these results should lead to consideration of treatment, minimizing public exposure, and the use of N95 respirators by handlers. These animals, however, under the guidelines are subject only to increased monitoring by culture and no isolation or movement restrictions.

There have been multiple examples of animals that have repeatedly remained culture negative, only to find significant gross lesions on post-mortem examination with subsequent positive culture. This may be a result of poor sample collection, storage, and submission procedures or a lack of shedding or intermittent shedding by the animal. I understood that we were utilizing the Stat-Pak and MAPIA tests to give us an early indication of positive animals to aid us in preventing transmission and to provide opportunities for earlier treatment. The change in the program to the new guidelines actually increases our risk of transmission by exposed, infected animals not yet found to

be culture positive. Previously these animals were grouped in Class C and as such were restricted in movement and afforded prophylactic treatment. Now these same animals housed directly with positive culture animals are unrestricted in their movement. It appears that the program has gone backwards in this regard.

While we understand that the culture offers the highest degree of specificity, and is the definitive test to determine an animal's positive status, under our current program, it has performed poorly in its sensitivity. If we believe the Stat-Pak MAPIA positive animal is at higher risk of being infected, these animals should be considered suspect and isolated from known positive animals and restricted in movement. These animals could be released from movement restriction after a period of isolation and subsequent negative testing.

Although we understand the rationale that a negative culture may indicate that an animal is not shedding and is thus not a risk to other animals, our experience with negative culture in animals with long term infection, the value of the Stat-Pak MAPIA in identifying high risk animals, and the uncertainty of animals reaction to treatment, that may or may not be in accordance with the guidelines, all lead us to believe that Stat-Pak MAPIA positive animals need to be held for additional testing prior to movement and comingling with other animals.

Please do extend my personal thanks to the subcommittee members for providing their expertise and considerable effort in developing these guidelines. As a state animal health official charged with protecting both animal and public health, these guidelines are extremely important in serving as a basis for actions we take with respect to tuberculosis in elephants.



u.s.elephantworkinggroup.xls

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

Species	Sex	Traveling	Scheduled	Stat-Pak resu Mapia results
AF	F		Sept. 2010	
AF	F			
AF	F			
AF	M			
AF	F			
As	F		3/15/2010, dor R, MAPIA neg	
As	F			NR
As	F			NR
AF	F		16-Mar	NR
As	F			NR
As	F		Jan-11	
As	F			
As	M		Jan/Feb 2011	
As	F			
As	F			
AF	M			
AF	M			
AF	F			
AF	F			
AF	F		June, 2010	
AF	F			
AF	M			
AF	F		Dec.-2010	
AF	F			
AF	M			
AF	F			
AF	F			
As	F		3/1/2010, don	NR
As	F			NR
As	F	T	Jan, 2011	
As	F	T		
As	F	T	Oct,2010	
As	M	T		
As	M	T		
As	F	T		
As	F	T		
As	F	T		
As	F	T		
As	F	T		
AF	F		April/May 201	NR
AF	F			NR
As	M		July, 2010	NR
AF	F		Jan, 2011	
AF	F			
As	M		May 19,2010	NR
As	F			R
As	F			
As	F			
As	F			NR
AF	F			NR
AF	F			NR
AF	F			NR
AF	F			NR
AF	F			NR

As	F		May-10	NR	
As	F			NR	
AF	F			NR	
As	F			NR	
As	F			NR	
As	M			NR	
As	F			NR	
As	F			R?	
As	F			NR	
AF	M		Done	NR	
AF	F			NR	
AF	M		nursing calf	NT	
AF	M			NR	
AF	F			NR	
AF	F			NR	
AF	F			NR	
AF	F			NR	
AF	M			NR	
AF	F				
AF	M				
AF	F			NR	
AF	M		nursing calf	NT	
AF	F				
AF	M				
As	F		May, 5 2010	NR	
As	F			NR	
AF	F		Jul-10		
AF	F				
AF	F				
As	F		Mar-10	NR	
As	F			NR	
As	F	T	3/4/2010	NR	
As	F	T		reactive	Mapia -
AF	F	T		NR	
AF	F	T			
AF	F	T			
AF	F	T			
AF	F	T			
AF	F	T			
As	F	T	done	R	Mapia +
AF	F	T			
As	F	T			
As	F	T			
AF	F	T			
As	F	T	May-10		
As	F	T			
As	F	T			
AF	F		Nov-10		
AF	F				
AF	F				
AF	M				
As	M		May-10	NR	
AF	F	T	done	NR	
AF	F		done	NR	
AF	F			NR	

AF	M			NR
AF	M			NR
AF	F			NR
AF	F	T		
AF	F	T		
AF	F		Done NVSI	NR
AF	F			NR
AF	F			NR
AF	M			NR
As	F	T		R
AF	F		?	
AF	F			
AF	M			
AF	M			
AF	F			
AF	F			
AF	F			
As	M	T	?	
AF	F		Oct. 2010	
AF	F			
As	F		Oct. 2010	
As	F			
As	F		Oct-10	
As	F			
AF	F		Done	NR
AF	F	T	?	
As	F		2011	
As	F			
AF	F		July 20,2010	
AF	F			
AF	F			
AF	F			
AF	M			
AF	M			
AF	F		Jul-10	
As	F			
AF	F		1-May	NR
AF	F			NR
AF	F		Aug-10	
AF	F			
AF	M		Jul-11	
AF	F			
As	F			
As	F		4-May	NR
As	F			R
As	F		April	R
As	F			NR
AF	F			NR
AF	F			NR
AF	M			NR
AF	F			NR
AF	F		?	
As	F	T		R,

MAPIA +

AF	F	T	Feb-11	
AF	M		Apr-10	NR
AF	F			NR
As	F		Jan-10	NR
As	F			NR
As	F			NR
As	F			NR
As	F			NR
As	F			R,known reac DPP -
As	F	T	Dec-10	
As	F	T		
AF	F		Dec-10	
AF	F			
As	F	T	Dec-10	
As	F	T		
As	M	T		
As	F	T		
As	F	T		
As	F	T		
As	F	T		
As	F	T		
As	F		Nov-10	
As	M			
As	F			
As	F			
As	F		Jan, 2011	
As	F			
As	M			
As	F	T		
As	F	T		
As	F	T		
As	F	T		
AF	F		NVSL	NR
AF	F			NR
AF	F		Dec. 2010	
AF	F			
AF	M			
AF	F			
As	F		Jan. 2010	R, previous case, treated
As	F			NR
As	F			NR
As	F			NR
As	M			NR
As	M			NR

As	F		NR
As	F		NR
As	F	May or June 2010	
As	F		R, MAPIA + previous case, see backgrou
As	F		
AF	F		NR
AF	F		NR
As	M	3/25/2010	R, MAPIA -
As	F		NR
As	F		NR
AF	M	Jan/Feb 2011	
AF	F		
AF	F		
AF	F		
AF	M		
AF	F		
AF	F	8/17,28,19/2010	
AF	F		
AF	F		
As	F	8/17,28,19/2010	
As	F		
As	F		
AS	M		
As	M		
AF	F	Apr-10	NR
AF	F		NR
AF	M		NR
As	F	Jan-11	
As	F		
As	F		
As	F	Nov-10	
As	F		T
As	F		T
As	F		T
As	M		T
As	M		T
As	F		
AF	F		
AS	F		T

AF	F			NR	
AF	F			NR	
AF	F		Sept/Oct 2010		
AF	F				
AF	F		late 2010		
AF	F				
AF	F				
AF	F				
AF	F				
As	F		Jan-11		
As	F				
As	F		Jan/Feb 2011		
As	F				
As	F				
As	M				
As	F				
As	F				
As	M		June,2010	NR	
As	F			NR	
AS	M			NR	
As	F			NR	
AS	M			NT	
AS	M			NR	
AF	F	T	Jan/Feb 2011		
As	F		July/Aug		
AS	F				
AF	F	T	Jan/Feb 2011		
AF	F	T			
AF	F		Sept/Oct 2010		
AF	F				
As	F	T	Feb-11		
As	F	T			
As	F	T			
As	M	T			
As	M	T			
As	F	T	May-10	NR	
As	F	T		R	MAPIA+*
As	F	T		R	MAPIA+*
As	F	T		NR	
As	F	T		R	
As	F	T		NR	
As	F	T		R	MAPIA+*
As	F	T		R	
As	F	T		NR	
As	F	T		NR	
As	F	T		R	
As	F	T		R	MAPIA+*
As	F	T		NR	
As	F	T		R	
As	F	T		R	MAPIA+*
As	F	T		NR	
As	F	T		R	
As	M	T		NR	
As	M	T		NR	
As	M	T		NR	
As	M	T		NR	

As	M	T		NR	
As	M	T		Not tested	
As	M	T		NR	
As	M	T		R	
As	F	T		NR	
AS	F	T		R	MAPIA+*
AS	F			NR	
AS	F	T		NR	
AS	F			NR	
As	F	T		NR	
As	F	T	Dec. 2010		
As	F	T			
As	F	T			
As	F	T			
As	F	T			
As	F	T			
As	F	T			
As	F	T			
As	F	T			
As	F	T			
As	F	T			
As	F	T			
As	F	T			
AS	F				
AS	F				
AS	M				
As	F	T			
AF	F		Jul-10		
AF	F				
AF	F				
AF	F				
As	F		Jul-10		
As	F				
As	F		Feb, 2011, Suki, May 2010		
As	F				
AF	F			NR	
AF	F			NR	
AF	F		Aug, 2010		
AF	F				
AF	F		Nov-10		
As	F		12-May-10 R		
As	F		Dec-10		
As	F				
As	F				
As	M				
As	F		Dec. 2010		
As	F				



Denise M
Sofranko/NM/APHIS/USDA
02/01/2010 10:03 AM

To Barbara A Kohn/MD/APHIS/USDA
cc
bcc
Subject Fw: Contacts for TB Guidelines

fyi

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

----- Forwarded by Denise M Sofranko/NM/APHIS/USDA on 02/01/2010 07:58 AM -----



(b)(6)
(b)(6)@flaquarium.
org>
02/01/2010 07:55 AM

To <Denise.M.Sofranko@aphis.usda.gov>,
(b)(6)@palmbeachzoo.org>
cc
Subject RE: Contacts for TB Guidelines

(b)(6)

The Florida Aquarium
701 Channelside Drive
Tampa, Florida 33602

(b)(6)@flaquarium.org
Cell (b)(6)
Office 813-367-4055
Home (b)(6)

G

(b)(6)

Veterinarian
PH: 813-273-(b)(6)
FAX: 813-273-4160



Please consider the environment - think before you print!

From: Denise.M.Sofranko@aphis.usda.gov [mailto:Denise.M.Sofranko@aphis.usda.gov]
Sent: Monday, February 01, 2010 9:52 AM

To (b)(6) palmbeachzoo.org; (b)(6)
Subject: Contacts for TB Guidelines

Good morning ladies!

I am trying to get the contact information on the Guidelines corrected for our web site.
Could you both give me the information you want included in Appendix 6?

thanks!

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Denise M
Sofranko/NM/APHIS/USDA
02/02/2010 06:15 PM

To Barbara A Kohn/MD/APHIS/USDA
cc
bcc
Subject Fw: Contacts for TB Guidelines

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

----- Forwarded by Denise M Sofranko/NM/APHIS/USDA on 02/02/2010 04:15 PM -----



(b)(6)
(b)(6)@palmbeachzoo.org
>
02/02/2010 04:03 PM

To <Denise.M.Sofranko@aphis.usda.gov>,
(b)(6)@flaquarium.org
cc
Subject RE: Contacts for TB Guidelines

(b)(6)

Palm Beach Zoo
1301 Summit Blvd
West Palm Beach, FL 33405
Phone: 561-833-7130 ext (b)(6)
Cell: (b)(6)
Email: (b)(6)@palmbeachzoo.org



From: Denise.M.Sofranko@aphis.usda.gov [mailto:Denise.M.Sofranko@aphis.usda.gov]
Sent: Monday, February 01, 2010 9:52 AM
To: (b)(6)@palmbeachzoo.org; (b)(6)@flaquarium.org
Subject: Contacts for TB Guidelines

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thanks!

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

Denise M
Sofranko/NM/APHIS/USDA
07/09/2009 05:13 PM

To Barbara A Kohn/MD/APHIS/USDA
cc
bcc
Subject Fw: Elephant TB Guidelines / USAHA TB Subcommittee
Report

This is good history.

Also, I thought (b)(6) was a member of the subcommittee but she was either added later or is one of their major consultants. I'll make sure we have that figured out before we finalize the letter.

----- Forwarded by Denise M Sofranko/NM/APHIS/USDA on 07/09/2009 03:12 PM -----



(b)(6)
(b)(6)@msn.co
m>
02/26/2008 10:05 AM

To "Denise Sofranko USDA Animal Care"
<Denise.M.Sofranko@aphis.usda.gov>
cc
Subject Fw: FW: Elephant TB Guidelines / USAHA TB Subcommittee
Report

You are welcome. I've included the e-mail that I sent out to Janet and the members of the Elephant TB Guidelines Subcommittee.

(b)(6)

Foxglove Consulting
522 Flora Vista Road NE
Olympia, WA 98506
home/office (b)(6)
e-mail (b)(6)@msn.com

----- Original Message -----

From: (b)(6)
To: (b)(6) [Disney vet](#) ; [Kathy Orloski USDA](#) ; [Janet.B.Payeur@aphis.usda.gov](#) ; [Chuck Massengill](#) ; [Ray Waters ARS USDA](#) ; [Mitch Palmer ARS USDA](#)
Cc: (b)(6)
Sent: Monday, February 25, 2008 10:45 PM
Subject: Re: FW: Elephant TB Guidelines / USAHA TB Subcommittee Report

Thanks to all of you for taking on this subcommittee's work. I've received good comments about the guidelines that you have revised.

(Seriously, (b)(6) is a really cool name.)

Now what?

Janet will compile any further changes and send me the final draft guidelines on Feb 28.

I will inform the rest of the TB Committee (b)(6) (since he requested the formation of this subcommittee) and USDA Animal Care that this subcommittee has finished its task and forward the final draft guidelines.

I'll send out subcommittee rules ("*Formation of Subcommittees of the USAHA TB Committee* "). I'll find out if/how this subcommittee can become a standing subcommittee, if that is what is necessary.

During the 2008 TB Committee meeting, I'll ask for a report from this subcommittee as well as the other subcommittees.

To move these guidelines forward, we may need a resolution.

Thanks again.

(b)(6)

Foxglove Consulting
522 Flora Vista Road NE
Olympia, WA 98506
home/office (b)(6)
e-mail (b)(6) @msn.com

----- Original Message -----

From: Janet.B.Payeur@aphis.usda.gov

To: (b)(6) Chuck Massengill <Chuck.Massengill@mda.mo.gov>, Kathy.A.Orloski@aphis.usda.gov, MitchellPalmer <mitchell.palmer>

Cc: drkathleenconnell@msn.com

Sent: Friday, February 22, 2008 3:36 PM

Subject: Re: FW: Elephant TB Guidelines / USAHA TB Subcommittee Report

(b)(6) Chuck, Kathy, Mitch, Ray

Attached are the comments that I have received from the old TB elephant working group members. I will change (b)(6) affiliation. Does the group want to make any other changes based on the comments? Animal Care would like us to proceed with getting these guidelines out as soon as possible since the Chembio test is now available at the NVSL. Please send me any recommendations by 2-26-08. If I do not here from you, I will assume no changes need to be made and send the current draft with out changes to (b)(6) on 2-28-08.

(See attached file (b)(6) 2-18-08.doc)(See attached file (b)(6) 2-19-08.doc)(See attached file: RS (b)(6) comments 2-21-08.doc)(See attached file: TBGuidelinesFeb12008draft-USAHA jm.doc)

(b)(6) I think the old working group needs to see the subcommittee guidelines on membership so that they don't assume that if they join USAHA and request to be on the TB committee that they will automatically be put on this new elephant guidelines subcommittee. Could you send something out soon to tell everyone how this is going to work?

I have also heard from most of the members of the current group, that they think this group should be ongoing (similar to the TB Scientific committee) and have some core members for Animal Care to consult with on different issues throughout the year. Is this possible?

Janet B. Payeur DVM, MPH, PhD
Scientific Outreach Coordinator
National Veterinary Services Laboratories
1800 Dayton Avenue
Ames, IA 50010

515-663-7003

Fax 515-663-7397

E-mail: Janet.B.Payeur@aphis.usda.gov

Denise M
Sofranko/NM/APHIS/USDA
07/09/2009 04:58 PM

To Barbara A Kohn/MD/APHIS/USDA
cc
bcc
Subject Fw: Question about a Subcommittee's work

Went back to some old e-mails for some history. This is a good synopsis. I'll send more if I find them useful.

----- Forwarded by Denise M Sofranko/NM/APHIS/USDA on 07/09/2009 02:58 PM -----



(b)(6)
msn.co
m>
03/20/2008 11:41 AM

To (b)(6)@usaha.org>
cc "Janet Payeur NVSL" <janet.b.payeur@usda.gov>, "Denise Sofranko USDA Animal Care" <Denise.M.Sofranko@aphis.usda.gov>, (b)(6)@michigan.gov, (b)(6)@aol.com>:elephant TB Working Group"
Subject Re: Question about a Subcommittee's work

Thanks. We'll shoot for the 2008 Annual Meeting to get approval.

I can't even imagine trying to convene a quorum of the TB Committee or asking for a special meeting of the USAHA BOD prior to October. That makes my head hurt.

We'll go with posting the final draft guidelines on the web (thank you for doing that) and distributing them to interested parties as a final draft document. Prior to the 2008 October meeting, the Subcommittee and the TB Committee will figure out internally how we want to proceed with these guidelines.

Thanks again.

(b)(6)

Foxglove Consulting
522 Flora Vista Road NE
Olympia, WA 98506
home/office (b)(6)
e-mail (b)(6)@msn.com

----- Original Message -----

From: (b)(6)
To: (b)(6)
Sent: Thursday, March 20, 2008 9:53 AM
Subject: RE: Question about a Subcommittee's work

(b)(6)

The Annual Meeting would be the best place for approval, though if you are able to convene a quorum, the committee can approve the guidelines. However, it wouldn't become official until BOD approval of the TB Committee report, which would take place at the meeting. To be technical, the President could call a special meeting of the BOD prior to October, but that is a challenging process and I am told it's historically not favored by the members of the Board.

We will post the guidelines on the web, albeit as "Draft" status. And for practical purposes, it is fine to distribute to those interested as a completed draft.

Thanks for all your work. Hope this helps,

(b)(6)

From: Kathleen CONNELL [mailto:drkathleenconnell@msn.com]

Sent: Thursday, March 20, 2008 11:11 AM

To: (b)(6) USAHA

Cc: (b)(6) Janet Payeur NVSL; (b)(6) Elephant TB Working Group; (b)(6)

(b)(6) Denise Sofranko USDA Animal Care

Subject: Re: Question about a Subcommittee's work

Thank you for your thorough and prompt reply. I will ensure that the Subcommittee has this information (via the Chair, who is one of the cc's).

Last year, (b)(6) told me that official USAHA business can only be conducted during the annual meetings. If that is the case, then the entire TB Committee can only approve this document at the October 2008 meeting. Is that correct?

Could these guidelines be posted on the USAHA web site? (b)(6) asked me that in a previous e-mail, but I wanted to clarify all these questions first. I attached a copy of the guidelines in case you needed them again.

Thanks again.

(b)(6)

Foxglove Consulting
522 Flora Vista Road NE
Olympia, WA 98506
home/office (b)(6)

e-mail (b)(6) @msn.com

----- Original Message -----

From: (b)(6)

To: (b)(6)

Cc: (b)(6) (b)(6) USAHA (b)(6) Janet Payeur NVSL; (b)(6) Elephant TB Working Group; (b)(6) Denise Sofranko USDA Animal Care

Sent: Thursday, March 20, 2008 8:59 AM

Subject: RE: Question about a Subcommittee's work

(b)(6)

Thanks for the note, good questions. I double checked with (b)(6) to make sure the process is correct, so below are answers to your questions in red.

Does the TB Committee have any additional responsibility or role in this?

The committee should approve the Subcommittee report. Beyond that, it's only as far as the committee wants to take it, ie resolutions/recommendations.

Does the entire TB Committee need to vote on acceptance of these guidelines?

Yes, it would be best for the committee to approve the report of the Subcommittee, then it becomes "official" action of the committee, and documented in the proceedings. I think it would also be pertinent for the Committee to recommend the use of these guidelines by whomever deemed fit. The TB Committee report is approved by the Board of Directors, and thus carries USAHA's acceptance.

Does the TB Committee need to hear a resolution on these guidelines?

Only if the Committee seeks action on behalf of the association, such as having USAHA resolve that USDA (or other agencies/organizations) adopt these guidelines.

Do a resolution and these guidelines, if approved by the entire TB Committee, then need to be officially passed on to the entire USAHA membership for consideration?

If seeking a USAHA resolution, yes, it would need to be approved by the membership. Otherwise, the guidelines themselves do not need to be approved by the general membership. Refer back to the BOD approval.

As the TB Committee Chair, is there anyone else I need to provide with these guidelines?

No, since you've shared with the committee and the office (for keeping records), I would say your duty has been fulfilled, unless you proceed with a resolution.

And, finally, the Elephant TB Working Group Chair (b)(6) asked if I would appoint the Subcommittee to take on this project. Can I share the Subcommittee's guidelines with the Elephant TB Working Group? The Elephant TB Working Group is not a USAHA Committee or Subcommittee. It has its origins in the American Association of Zoo Veterinarians (AAZV). While not an AAZV Committee, many of the Elephant TB Working Group participants are AAZV members.

I think it would be fine to share with the Elephant TB working group, as long as it is communicated that it's still a draft. Once the committee approves it, and the BOD approves their report, then it can be finalized. That's USAHA's role at its best-creating solutions to be used for a broader audience.

If you felt it would be useful to package this as a complete publication, once approved at the meeting, we could work on putting that together and distributing/making it available from the office if you think necessary. Please let me know if we can assist any further.

Regards,

(b)(6)

From: (b)(6) [mailto:(b)(6)@msn.com]

Sent: Wednesday, March 19, 2008 2:34 PM

To: (b)(6)

Cc: (b)(6) USAHA; (b)(6); Janet Payeur NVSL; (b)(6) Elephant TB Working Group; (b)(6) Denise Sofranko USDA Animal Care

Subject: Question about a Subcommittee's work

During the last TB Committee meeting at the 2007 USAHA meeting, a Subcommittee was established to review and revise guidelines on elephant TB. The Subcommittee did just that and now has its final draft, "Guidelines for the Control of Tuberculosis in Elephants". I have disseminated the document to the entire TB Committee, with you included in the cc of the e-mail. The Subcommittee Chair will report on the Subcommittee's work during the 2008 TB Committee meeting.

Questions I have:

Does the TB Committee have any additional responsibility or role in this?
Does the entire TB Committee need to vote on acceptance of these guidelines?
Does the TB Committee need to hear a resolution on these guidelines?
Do a resolution and these guidelines, if approved by the entire TB Committee, then need to be officially passed on to the entire USAHA membership for consideration?
As the TB Committee Chair, is there anyone else I need to provide with these guidelines?

And, finally, the Elephant TB Working Group Chair (b)(6) asked if I would appoint the Subcommittee to take on this project. Can I share the Subcommittee's guidelines with the Elephant TB Working Group? The Elephant TB Working Group is not a USAHA Committee or Subcommittee. It has its origins in the American Association of Zoo Veterinarians (AAZV). While not an AAZV Committee, many of the Elephant TB Working Group participants are AAZV members.

(b)(6) asked if I wanted to have the guidelines on the USAHA Web site. Yes, but I wanted to get some answers to my questions before the document was posted to make sure we were all "street legal".

Thanks.

(b)(6)

Foxglove Consulting
522 Flora Vista Road NE
Olympia, WA 98506
home/office (b)(6)
e-mail (b)(6) @msn.com



Denise M
Sofranko/NM/APHIS/USDA
06/08/2009 03:21 PM

To Barbara A Kohn/MD/APHIS/USDA
cc
bcc
Subject Fw: Stat-Pak license

fyi

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

----- Forwarded by Denise M Sofranko/NM/APHIS/USDA on 06/08/2009 01:23 PM -----



Larry R
Ludemann/IA/APHIS/USDA
06/08/2009 01:14 PM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc
Subject Re: Stat-Pak license

Dennis:

Manufacturers are not required to put all restrictions on the insert.

Larry Ludemann
Senior Staff Veterinarian
USDA, Center for Veterinary Biologics-Policy, Evaluation, Licensing
510 South 17th Street, Suite 104
Ames, IA 50010
(515) 232-5785
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
06/08/2009 02:09 PM

To Larry R Ludemann/IA/APHIS/USDA@USDA
cc
Subject Re: Stat-Pak license

Thanks Larry,

We're still working on using this test with the new guidelines and I had passed the wording on regarding the license. Because we couldn't find any kind of restrictions with the kit itself or packaging, the question came up about the license.

That's all I was asking for. No worries though. This whole issue has gone way above me by now. ;-)

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care
Larry R Ludemann/IA/APHIS/USDA



Larry R
Ludemann/IA/APHIS/USDA

To Denise M Sofranko/NM/APHIS/USDA@USDA



06/08/2009 12:32 PM

cc

Subject Re: Stat-Pak license 

Denise:

Without clear indications of the purpose of needing the actual letter or license, I have been asked to withhold giving you copies. The letter notifying the firm of the product license only indicates to note the restrictions on the license. You have been provided with the actual wording of the license restrictions.

Larry Ludemann
Senior Staff Veterinarian
USDA, Center for Veterinary Biologics-Policy, Evaluation, Licensing
510 South 17th Street, Suite 104
Ames, IA 50010
(515) 232-5785
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
06/01/2009 11:29 AM

To Larry R Ludemann/IA/APHIS/USDA@USDA

cc

Subject Stat-Pak license

Hi Larry,

Still working on the Stat-Pak issue here.

I've been asked to get the actual licensing notification that was given to Chem Bio for this test kit. I have the brief statement with restrictions of use that you sent in August of 2007 but is there a more complete notification or letter that was given to Chem Bio outlining restrictions of use and sale?

Thanks!

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Denise M
Sofranko/NM/APHIS/USDA
06/08/2009 02:45 PM

To Barbara A Kohn/MD/APHIS/USDA
cc
bcc
Subject Re: Fw: Stat-Pak license

Don't know and don't even know what to reply back.

I talked to (b)(6) (AAZV) this morning. He called about moving another elephant in with their lone one and at the end of the conversation, I just asked him when he thought they'd have the letter with their concerns into the Administrator. He thought by next week. I didn't get into a discussion of the substance but did tell him that if he had questions about any of this stuff in the future, he could feel free to call me and I would explain things as best as I could. I told him that I didn't want to discuss it now because this process of getting the letter in and us answering it was already on the go and I didn't want to interfere with it. I just wanted to know when to expect the letter. So we're probably looking at a month or so until we can even think about getting back on track. ;-)

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care
Barbara A Kohn/MD/APHIS/USDA



Barbara A
Kohn/MD/APHIS/USDA
06/08/2009 12:40 PM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc
Subject Re: Fw: Stat-Pak license

Interesting, indeed.... Wonder if John C is feeling some heat? Wonder what it is all about..

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
06/08/2009 02:38 PM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject Fw: Stat-Pak license

Interesting reply.

I think Chester said he is tracking this information down so I should just back off and leave it to someone else. What do you think?

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

----- Forwarded by Denise M Sofranko/NM/APHIS/USDA on 06/08/2009 12:39 PM -----



Larry R
Ludemann/IA/APHIS/USDA
06/08/2009 12:32 PM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc
Subject Re: Stat-Pak license 

Denise:

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Larry Ludemann
Senior Staff Veterinarian
USDA, Center for Veterinary Biologics-Policy, Evaluation, Licensing
510 South 17th Street, Suite 104
Ames, IA 50010
(515) 232-5785
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
06/01/2009 11:29 AM

To Larry R Ludemann/IA/APHIS/USDA@USDA
cc
Subject Stat-Pak license

Hi Larry,

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Thanks!

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Barbara A
Kohn/MD/APHIS/USDA
06/08/2009 02:40 PM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc
bcc
Subject Re: Fw: Stat-Pak license

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Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
06/08/2009 02:38 PM

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Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

----- Forwarded by Denise M Sofranko/NM/APHIS/USDA on 06/08/2009 12:39 PM -----



Larry R
Ludemann/IA/APHIS/USDA
06/08/2009 12:32 PM

To Denise M Sofranko/NM/APHIS/USDA@USDA
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Larry Ludemann
Senior Staff Veterinarian
USDA, Center for Veterinary Biologics-Policy, Evaluation, Licensing
510 South 17th Street, Suite 104
Ames, IA 50010
(515) 232-5785
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
06/01/2009 11:29 AM

To Larry R Ludemann/IA/APHIS/USDA@USDA
cc

Subject Stat-Pak license



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Thanks!

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Denise M
Sofranko/NM/APHIS/USDA
06/08/2009 02:38 PM

To Barbara A Kohn/MD/APHIS/USDA
cc
bcc

Subject Fw: Stat-Pak license

History: This message has been replied to.

Interesting reply.

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Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

----- Forwarded by Denise M Sofranko/NM/APHIS/USDA on 06/08/2009 12:39 PM -----



Larry R
Ludemann/IA/APHIS/USDA
06/08/2009 12:32 PM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc

Subject Re: Stat-Pak license

Denise:

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Larry Ludemann
Senior Staff Veterinarian
USDA, Center for Veterinary Biologics-Policy, Evaluation, Licensing
510 South 17th Street, Suite 104
Ames, IA 50010
(515) 232-5785
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
06/01/2009 11:29 AM

To Larry R Ludemann/IA/APHIS/USDA@USDA
cc

Subject Stat-Pak license

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Thanks!

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Denise M
Sofranko/NM/APHIS/USDA
06/01/2009 02:09 PM

To Barbara A Kohn/MD/APHIS/USDA
cc
bcc
Subject Fw: Chembio Elephant Stat-Pak license

I can't remember if I sent this to you or not. Things are just flying around like crazy here this morning.

I've written to Larry Ludeman to see if there was a letter or notification or something sent to Chem Bio with the restrictions spelled out. I would think so.

I'll let you know as soon as I get something.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

----- Forwarded by Denise M Sofranko/NM/APHIS/USDA on 06/01/2009 12:10 PM -----



Jeffrey T
Nelson/IA/APHIS/USDA
06/01/2009 10:16 AM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc
Subject Re: Fw: Chembio Elephant Stat-Pak license

Denise,

Here is the website for the TB Stat-Pak insert: <http://www.chembio.com/pdfs/ElephantTB5Kit.pdf>

I did not see anything there or on the box that discusses what Larry mentioned or anything else about the licensing of the test. It did have a License number on the insert.

Hopefully this helps!

Jeffrey T. Nelson, DVM
VMO, Serology Section
National Veterinary Services Laboratories
1800 Dayton Avenue
Ames, IA 50010

Office: 515-663-7966

Cell (b)(6)

Fax: 515-663-7569

E-mail: Jeffrey.T.Nelson@aphis.usda.gov

Denise M Sofranko/NM/APHIS/USDA

Denise M
Sofranko/NM/APHIS/USDA
06/01/2009 11:02 AM

To Jeffrey T Nelson/IA/APHIS/USDA@USDA
cc
Subject Fw: Chembio Elephant Stat-Pak license

Hey Jeff,

We're trying to get all the pertinent language on the licensing for the Stat-Pak. The following e-mail is the language Larry sent me when the test was licensed.

Is there anything more on the box or on the insert with anything else about the licensing? If so, could you make a copy or scan and send it to me?

My fax number is 505.293.7466

thanks!!!!

----- Forwarded by Denise M Sofranko/NM/APHIS/USDA on 06/01/2009 10:01 AM -----



Larry R
Ludemann/IA/APHIS/USDA
08/15/2007 10:19 AM

To Denise M Sofranko/NM/APHIS/USDA@USDA, Thomas O
Bunn/IA/APHIS/USDA@USDA
cc Rick E Hill/IA/APHIS/USDA@USDA, LeeAnn
Thomas/MD/APHIS/USDA@USDA
Subject Chembio Elephant Stat-Pak license

Chembio Inc., Medford, New York was issued a license on August 15, 2007, for sale and distribution of Mycobacterium Bovis-Mycobacterium Tuberculosis Antibody Test Kit, Trade Name Elephant Stat-Pak. This kit is intended as an aid in the diagnosis of tuberculosis from elephant serum or plasma. The following licensing restrictions have been placed on this kit:

- For use by, or under the supervision of, a veterinarian
- Sale and use in the United States restricted to laboratories approved by state and federal (USDA) animal health officials

Larry Ludemann
Senior Staff Veterinarian
Center for Veterinary Biologics-Policy, Evaluation, Licensing



Denise M
Sofranko/NM/APHIS/USDA
09/02/2008 02:50 PM

To Barbara A Kohn/MD/APHIS/USDA
cc
bcc
Subject Fw: USAHA

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

----- Forwarded by Denise M Sofranko/NM/APHIS/USDA on 09/02/2008 12:49 PM -----



(b)(6)
msn.co
m>
09/02/2008 12:37 PM

To <Denise.M.Sofranko@aphis.usda.gov>
cc
Subject Re: USAHA

I cc'd you on my Aug 20 e-mail that had all the details. If you need me to resend it so you have the details for your records, let me know.

I've heard back from Janet. She will have (b)(6) give an update report for the Subcommittee and we can enter the guidelines into the official report. All 5 Subcommittees have 10 mins on the agenda to give reports.

Janet and the members of the Subcommittee are to work on:

1. a final report
2. the final guidelines (needed 2 minor changes last time I saw them---delete (b)(6) personal contact info, change the date from 2007 in the title to 2008)
3. a resolution, if Janet and the Subcommittee decides it needs one (only necessary if the TB Committee seeks action on behalf of USAHA, such as having USAHA encourage that XXX agency or XXX organization adopt these guidelines.)
4. Determining if this Subcommittee needs to be disbanded after the 2008 USAHA meeting or continue on as a Subcommittee, like the TB SAS.

As TB Committee Chair, I will accept the report and the guidelines (if it's moved, seconded and passed to do so) and both will be included in the TB Committee's report. I then forward the TB Committee report to the USAHA Board of Directors for acceptance and approval and the guidelines become part of the official USAHA proceedings.

(b)(6)

Foxglove Consulting
522 Flora Vista Road NE
Olympia, WA 98506
home/office (b)(6)
e-mail (b)(6)@msn.com

----- Original Message -----

From: Denise.M.Sofranko@aphis.usda.gov

To: (b)(6)

Sent: Monday, August 25, 2008 12:01 PM

Subject: USAHA

Hi (b)(6)

I understand that Janet is on vacation right now but have you gotten any feedback from her or her subcommittee on how they are going to handle the issue of the Elephant TB guidelines? I'm assuming they'll draft a resolution but haven't gotten confirmation on that.

Also, is there any other discussion of elephant TB on the TB committee agenda for this year?

thanks!

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Denise M
Sofranko/NM/APHIS/USDA
02/20/2008 02:45 PM

To Barbara A Kohn/MD/APHIS/USDA
cc
bcc
Subject Fw: Elephant Tb Guidelines / USAHA Tb Subcommittee
Report

fyi

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

----- Forwarded by Denise M Sofranko/NM/APHIS/USDA on 02/20/2008 12:38 PM -----



(b)(6)
(b)(6)@chembio.com>
02/20/2008 02:37 PM

To (b)(6)@aol.com>, (b)(6)@ucdavis.edu>,
(b)(6)@disnev.com>,
(b)(6)@BuschGardens.com>,
(b)(6)@yahoo.com>,
<Denise.M.Sofranko@aphis.usda.gov>,
(b)(6)@yahoo.com>,
<Janet.B.Paveur@aphis.usda.gov>,
(b)(6)@med.va.gov>, (b)(6)@
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(b)(6)@vetmed.ufl.edu>, (b)(6)@ucdavis.edu>,
(b)(6)@calacademy.org>, (b)(6)@disney.com>,
(b)(6)@feldinc.com>,
(b)(6)@MissouriState.edu>,
<rwaters@NADC.ARS.USDA.GOV>,
(b)(6)@elephantcare.org>

cc

Subject RE: Elephant Tb Guidelines / USAHA Tb Subcommittee
Report

Members of the Elephant TB Guideline Update Working Group,

(b)(6) has asked me to respond to a question concerning availability of Chembio's ElephantTB STAT-PAK[®] Assay though NVSL. There was a memorandum (see attached) that was disseminated; I'm not sure to what extent, indicating that NVSL was prepared to begin accepting serum samples for serological testing for TB using the Chembio ElephantTB STAT-PAK Assay kit. I received the letter on January 12, 2008 and it was co-signed by Jeffery T. Nelson, Steven Hennager, and David Kinker within the Serology Section at NVSL. To date NVSL has purchased and Chembio has completed shipment of 110 devices to NVSL.

Regards,

(b)(6)

(b)(6)

Veterinary TB

Chembio Diagnostic Systems, Inc.
3661 Horseblock Road
Medford, New York 11763
Tel: (631)-924-1135 Ext. (b)(6)
Fax: (631)-924-6033
Mobile (b)(6)
e-mail (b)(6) @chembio.com
website: www.chembio.com

----- Message from (b)(6) aol.com> on Mon, 11 Feb 2008 17:05:50 -0500 -----

(b)(6) ucdavis.edu>, (b)(6) @aol.com>, <(b)(6))disney.com>,
(b)(6))BuschGardens.com>, (b)(6) yahoo.com>,
<Denise.M.Sofranko@aphis.usda.gov>, (b)(6))yahoo.com>,
<Janet.B.Payeur@aphis.usda.gov>, (b)(6) med.va.gov>, (b)(6)
To: (b)(6))chembio.com>, (b)(6) @vetmed.ufl.edu>, (b)(6))ucdavis.edu>,
(b)(6) @calacademy.org>, (b)(6) @disney.com> (b)(6))feldinc.com>,
(b)(6))MissouriState.edu>, <rwaters@NADC.ARS.USDA.GOV>,
(b)(6))elephantcare.org>

Subject: Elephant Tb Guidelines / USAHA Tb Subcommittee Report

Dear Elephant Tb Working Group, the USAHA Tuberculosis subcommittee has completed their review of the Elephant Tb Guidelines and has sent the document back to us for comment. I have attached the document with their comments. Would you please review the document and send your comments to Dr. Payeur, Chair of the USAHA Tb subcommittee and myself by February 20.

The USAHA Tb subcommittee members who worked with the document were: (b)(6), Chuck Massengill, Mitch Palmer, Kathy Orloski, Ray Waters, and Janet Payeur. This subcommittee is recommending that the Elephant Tb Working Group be kept under the TB Committee of the USAHA. This would require members of the Elephant Tb Working Group to be members of the USAHA and the TB Committee. Subject matter experts could be brought in as needed for specific questions or concerns and not have to be official members of the USAHA at the request of the Chair.

I look forward to receiving your comments on the attached document in a timely manner. Thanks in advance for your input. Wilbur

(b)(6)

(b)(6) Elephant TB Working Group
6 North Pennell Road
Media, PA 19063
Phn. 610-892-(b)(6)
Fax: 610-892-4813
E-mail: (b)(6))aol.com

The year's hottest artists on the red carpet at the Grammy Awards. AOL Music takes you there.



Elephant Stat-Pak NVSL Letter.doc



United States
Department of
Agriculture

Animal and Plant
Health Inspection
Service

Veterinary Services

National Veterinary
Services Laboratories

Diagnostic
Bacteriology
Laboratory

Serology Section

1800 Dayton Avenue
P.O. Box 844
Ames, IA 50010

(515) 663-7563
FAX (515) 663-7569

Federal Relay Service
(Voice/TTY/ASCII/Spanish)
1-800-877-8339

To Whom It May Concern:

The Serology Section of the National Veterinary Services Laboratories (NVSL) is now offering the Chembio Diagnostic Systems, Inc. ElephantTB STAT-PAK® for testing elephants for antibodies for *Mycobacterium tuberculosis* and *Mycobacterium bovis*. Submitters that would like to have this test performed can collect whole blood, serum or plasma. The test requires a small amount of sample, however, NVSL would prefer 2-3mls of serum so it could be banked and utilized for proficiency panels or in the development of future tests. Submit your sample to NVSL with a standard submission form (VS Form 10-4). Copies of this submission form can be found at the following web address:

http://www.aphis.usda.gov/animal_health/lab_info_services/downloads/VS_Form10-4.pdf

Samples should be shipped on cold packs overnight the day they are collected. Results can be expected in 1-2 business days. Based on the initial pricing established by Chembio for these tests, the initial NVSL user fee will be \$208 per sample. Please call ahead at 515-663-7563 prior to collecting the samples to verify we are able to process them in a timely manner.

In order to better meet the demands of our customers and prevent delays in testing, NVSL is requesting your assistance in determining the annual demand for this test. Please provide us the number of elephants you anticipate testing annually by this test by contacting Dr. Jeffrey Nelson or Mr. Steven Hennager.

Jeffrey Nelson, DVM
jeffrey.t.nelson@aphis.usda.gov
(515)663-7966

Mr. Steven Hennager
steven.g.hennager@aphis.usda.gov
(515)663-7951

Sincerely,

David Kinker, D.V.M.
Serology Section Head



Safeguarding American Agriculture

APHIS is an agency of USDA's Marketing and Regulatory Programs
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Denise M
Sofranko/NM/APHIS/USDA
02/11/2008 05:15 PM

To Ray M Flynn/CO/APHIS/USDA@USDA, Barbara A
Kohn/MD/APHIS/USDA
cc
bcc
Subject Fw: Elephant Tb Guidelines / USAHA Tb Subcommittee
Report

fyi

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

----- Forwarded by Denise M Sofranko/NM/APHIS/USDA on 02/11/2008 03:08 PM -----



(b)(6) aol.com
02/11/2008 05:05 PM

To (b)(6) ucdavis.edu, (b)(6) aol.com,
(b)(6) @disney.com,
(b)(6) @BuschGardens.com,
(b)(6) yahoo.com, Denise.M.Sofranko@aphis.usda.gov,
(b)(6) @vahoo.com, Janet.B.Payeur@aphis.usda.gov,
(b)(6) @med.va.gov (b)(6) @chembio.com,
(b)(6) @vetmed.ufl.edu (b)(6) @ucdavis.edu,
(b)(6) @calacademy.org, (b)(6) @disney.com,
(b)(6) @feldinc.com, (b)(6) @MissouriState.edu,
rwaters@NADC.ARS.USDA.GOV,
(b)(6) elephantcare.org

cc

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The year's hottest artists on the red carpet at the Grammy Awards. AOL Music takes you there.



TBGuidelinesFeb1,2008draft-USAHA.doc



Denise M
Sofranko/NM/APHIS/USDA
02/08/2008 05:49 PM

To Barbara A Kohn/MD/APHIS/USDA
cc
bcc
Subject Fw: Elephant TB serologic test (ElephantTB STAT-PAK)
update

fyi

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

----- Forwarded by Denise M Sofranko/NM/APHIS/USDA on 02/08/2008 03:42 PM -----



(b)(6)
@disney.com
>
02/08/2008 04:34 PM

To (b)(6) @googlegroups.com (b)(6)
(b)(6) @chembio.com,
(b)(6) @clevelandmetroparks.com, (b)(6)
(b)(6) @detroitzoo.org,
(b)(6) @sandiegozoo.org, (b)(6)
(b)(6) @scz.org, (b)(6) @msn.com,
(b)(6) @wcs.org, (b)(6)
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(b)(6) @hotmail.com, (b)(6) @gov,
(b)(6) @runners.com, (b)(6) @zoo.org,
(b)(6) @LowryParkZoo.com,
(b)(6) @hotmail.com, (b)(6)
(b)(6) @smsu.edu, (b)(6) @itl zoo.org,
(b)(6) @indy zoo.com, (b)(6) @sandiegozoo.org,
(b)(6) @omahazoo.com,
(b)(6) @anheuser-busch.com,
(b)(6) @toledo zoo.org (b)(6) @zoo.pgh.pa.us,
(b)(6) @aol.com, (b)(6) @utk.edu
(b)(6) @metro.dst.or.us (b)(6)
(b)(6) @disney.com,
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(b)(6) @sfzoo.org, (b)(6)
(b)(6) @czoo.com,
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(b)(6) @torontozoo.c (b)(6) @cornell.edu,
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(b)(6) @phillyzoo.org, (b)(6) @gea.org,
<hospital@buffalozoo.org>
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(b)(6) @wcs.org,
<Janet.B.Payeur@aphis.usda.gov>
(b)(6) @houstonzoo.org, (b)(6) @med.va.gov,
(b)(6) @anheuser-busch.com,
(b)(6) @sandiegozoo.org (b)(6) @indy zoo.com,
(b)(6) @utk.edu (b)(6) @stlzoo.org,
(b)(6) @rochester.rr.com (b)(6) @sandiegozoo.org,
(b)(6) @oaklandzoo.org (b)(6)
(b)(6) @riverbanks.org, (b)(6) @lpzoo.org,
(b)(6) @thephxzoo.com (b)(6) @si.edu, (b)(6)
(b)(6) @vmth.ucdavis.edu,
(b)(6) @ucdavis.edu, (b)(6) @sandiegozoo.org,
(b)(6) @zooatlanta.org,
(b)(6) @cincinnati zoo.org, (b)(6)
3) (b)(6) @stlzoo.org, (b)(6) @colszoo.org,



(b)(6)@crc.si.edu>, (b)(6)@marylandzoo.org>, (b)(6)@nczoo.org>, (b)(6)@yahoo.com>, (b)(6)@colszoo.org>, (b)(6)@cabq.gov>, (b)(6)@sandiegozoo.org>, (b)(6)@houstonzoo.org>, (b)(6)@nail.mnzoo.state.mn.us>, (b)(6)@cornell.edu>, (b)(6)@fortworthzoo.org>, (b)(6)@disney.com>, (b)(6)@sandiegozoo.org>, (b)(6)@sandiegozoo.org>, (b)(6)@sentex.net>, (b)(6)@sandiegozoo.org>, (b)(6)@theplxzoo.com", (b)(6)@auduboninstitute.org>, (b)(6)@earthlink.net>, (b)(6)@cs.org>, (b)(6)@stlzoo.org>, (b)(6)@MedImmune.com>, <rmcm3@bellsouth.net>, (b)(6)@email.disney.com>, (b)(6)@ju.edu>, (b)(6)@sandiegozoo.org>, (b)(6)@ucdavis.edu>, (b)(6)@denverzoo.org>, (b)(6)@fortworthzoo.org>, (b)(6)@nzp.si.edu>, (b)(6)@haffeezoo.org>, (b)(6)@yahoo.com>, (b)(6)@disney.com>, (b)(6)@nzp.si.edu>, (b)(6)@aol.com>, (b)(6)@sandiegozoo.org>, (b)(6)@dallascityvhall.com>, (b)(6)@gmail.com>, (b)(6)@BrookfieldZoo.org>, (b)(6)@execpc.com>, <vet@zoogranby.qc.ca>, (b)(6)@aol.com>, (b)(6)@aol.com>, (b)(6)@juno.com>, <ZooGai@aol.com>, <zoosrvet@sazoo-aq.org>, <zoovet@denverzoo.org>, (b)(6)@jaxzoo.org>, (b)(6)@jaxzoo.org>, <Denise.M.Sofranko@aphis.usda.gov>, (b)(6)@missouristate.edu>, <epi@lpzoo.org>, (b)(6)@mail.vetmed.ufl.edu>, (b)(6)@chembio.com>, (b)(6)@gmail.com>, (b)(6)@aphis.usda.gov>, (b)(6)@disney.com>, (b)(6)@FELDINC.COM>, (b)(6)@zoo.org>, (b)(6)@admin@lionsafari.com>, (b)(6)@demi.com>, (b)(6)@sftp.com>, (b)(6)@aol.com>, (b)(6)@zoo.org>, (b)(6)@etro.dst.or>, (b)(6)@scz.org>, (b)(6)@sandiegozoo.org>, (b)(6)@sazoo-aq.org>

cc

Subject Elephant TB serologic test (ElephantTB STAT-PAK) update

Hi all,

Many of you may have received a letter from (b)(6) of NVSL regarding the availability of Chembio's Elephant TB STAT-PAK test. To clarify, the 2003 USDA guidelines for testing elephants are still the current standard for testing and monitoring elephants (

http://www.aphis.usda.gov/animal_welfare/downloads/elephant/tb2003.pdf). However, the National TB Working Group for Zoos has been actively reviewing and revising these guidelines for the last couple years and have submitted these for scientific review to the US Animal Health Association's TB Committee. It is expected that changes will be back and revisions made this spring.

In the meantime, serological testing of elephants is VOLUNTARY and results are not required to be reported at this time. Unless required in future revisions of the guidelines, it is at your discretion to have this testing performed. However, if you choose to do so, a single serum sample collected at the time of the trunk wash samples is recommended. Additional information on interpretation of results and further monitoring can be provided by the Elephant SSP Veterinary Advisory. Other references are also available for understanding these tests (see list below). Updates will be provided as they become available.

Please feel free to contact me with any specific questions.

Sincerely

(b)(6)

1. Lyashchenko, K., Miller, M., and W.R. Waters. 2005. Application of MAPIA (Multiple Antigen Print Immunoassay) and Rapid Lateral Flow Technology for Tuberculosis Testing of Elephants. *Proc. AAZV, AAWV, AZA/NAG Joint Confer.* Pp. 64-65.
2. Lyashchenko, K., Greenwald, R., Esfandiari, J., Olsen, J.H., Ball, R., Dumonceaux, G., Dunker, F., Buckley, C., Richard, M., Murray, S., Payeur, J., Andersen, P., Pollock, J.M., Mikota, S., Miller, M., Sofranko, D., and Waters, W.R. 2006. Tuberculosis in elephants: antibody responses to defined antigens of *Mycobacterium tuberculosis*, potential for early diagnosis, and monitoring of treatment. *Clin. Vacc. Immunol.* 13:722-732.
3. Moller, T., Roken, B., Petersson, L. et al. 2005. Preliminary Results of a New Serological Test for Detection of TB Infection (*Mycobacterium tuberculosis*) in Elephants (*Elephas maximus* and *Loxodonta africanum*): Swedish case studies. *Verh Erkg Zootiere* 42:173-181.



(b)(6)
(b)(6) @palmbeachzoo.org
>
06/17/2010 05:15 AM

To <Janet.B.Payeur@aphis.usda.gov>,
<rwaters@nadc.ars.usda.gov>,
(b)(6) @embarqmail.com>,
cc
bcc
Subject RE: elephant TB conference call

I can do Wed but have appts scheduled for Monday afternoon.
Michele

From: Janet.B.Payeur@aphis.usda.gov [mailto:Janet.B.Payeur@aphis.usda.gov]
Sent: Wednesday, June 16, 2010 7:23 PM
To: (b)(6) rwaters@nadc.ars.usda.gov; (b)(6) @embarqmail.com;
Kathy.A.Orloski@aphis.usda.gov; (b)(6) elephantcare.org; Denise_M_Sofranko@aphis.usda.gov;
Barbara.A.Kohn@aphis.usda.gov
Subject: elephant TB conference call
Importance: High

Looking at everybody's schedule for the next 2 weeks, there were several on vacation this week and hopefully the next week looks better. Please let me know if you are available, **Monday, Jun 21 at 2:30 PM central time or Wednesday, Jun 23 at 2:30 PM Central time?**

Janet B. Payeur DVM, MPH, PhD
Scientific Outreach Coordinator
National Veterinary Services Laboratories
1920 Dayton Avenue
Ames, IA 50010

515-337-7003
Fax 515-337-7397
E-mail: Janet.B.Payeur@aphis.usda.gov



Ray Waters
 <ray.waters@ars.usda.gov>
 04/09/2008 02:10 PM

To <Thomas.O.Bunn@aphis.usda.gov>,
 <Denise.M.Sofranko@aphis.usda.gov>
 cc <Barbara.A.Kohn@aphis.usda.gov>,
 <Charles.W.Hench@aphis.usda.gov>,
 <Jeffrey.T.Nelson@aphis.usda.gov>,
 bcc

Subject Re: Elephant TB Stat Pak: One more time

I like this solution - as mentioned, it follows the skin test model.
 ray

On 4/9/08 12:49 PM, "Thomas.O.Bunn@aphis.usda.gov" <Thomas.O.Bunn@aphis.usda.gov> wrote:

Ray,
 You caught something that we need to be clear on, and I think we may have intertwined two different solutions into one.

As originally written, the second bullet "Chembio sells only to approved laboratories (list provided by APHIS-AC)" appears to contradict the first paragraph where it says "allow the Stat-Pak to be sold to NVSL and approved laboratories and State and Federal Animal Health Agencies, or approved accredited veterinarians".

We had discussed that an accredited veterinarian could be approved as a "laboratory" to **conduct** the test after receiving adequate training and agreeing to report results in a specific manner. One solution was that they could also **purchase** the kit directly from Chembio (covered by the second bullet) and the other solution was that the kit would be sold to them by the NVSL and the cost recovered through user fees. It could also be distributed by State and Federal Animal Health Agencies, but the restriction on the license would have to be changed since agencies are not "approved laboratories". Distribution by the NVSL was the reason for the third bullet "Distribution model for PPD could be used."

If we are all in agreement that Chembio can sell to approved laboratories and that an accredited veterinarian can be an approved laboratory then I suggest the Solutions/Strategies be changed to read:

- Continue with current restrictions and allow the Stat-Pak to be sold only to approved laboratories.
- An accredited veterinarian may become an approved laboratory under protocols developed by AC.
- Chembio supplies records to AC and CVB for all kits sold in U.S.
- Samples for mandated annual test for elephants must be collected under State/Federal veterinary supervision and shipped to an approved State/Federal laboratory. The test may be conducted on site by an approved accredited veterinarian provided the test is observed by and the result is approved by a State/Federal veterinarian.
- Test form for on site tests by approved accredited veterinarians will be needed. All results must be available for review by Animal Care and Veterinary Services.

Ray Waters <ray.waters@ars.usda.gov> 04/09/2008 10:02 AM

To

<Denise.M.Sofranko@aphis.usda.gov>, <Thomas.O.Bunn@aphis.usda.gov>

cc

<Barbara.A.Kohn@aphis.usda.gov>, <Charles.W.Hench@aphis.usda.gov>, <Jeffrey.T.Nelson@aphis.usda.gov>,
 <Kathy.A.Orloski@aphis.usda.gov>, <Larry.R.Ludemann@aphis.usda.gov>, <LeeAnn.Thomas@aphis.usda.gov>, Ray Waters
 <rwaters@nadc.ars.usda.gov>

Subject

Re: Elephant TB Stat Pak: One more time

A minor suggestion (or question) for consideration highlighted with track changes tool in the attached document.
 Thanks
 ray

On 4/9/08 8:27 AM, "Denise.M.Sofranko@aphis.usda.gov" <Denise.M.Sofranko@aphis.usda.gov> wrote:

> Hopefully, I have everyone's comments by now. Please review again and see
> if this is something we can all agree to send forward. If not, let's
> discuss again so we can all be comfortable with this.
> thanks!
>
> (See attached file: Statpakissue409.doc)
>
>
> Denise M. Sofranko, DVM
> Field Specialist for Elephants
> USDA/APHIS/Animal Care

[attachment "Statpakissue409(rw).doc" deleted by Thomas O Bunn/IA/APHIS/USDA]

Calendar Entry

Meeting

Notify me Mark Private Pencil In

Subject Elephant TB Stat Pak testing - Elephant TB subcommittee of USAHA TB Committee

Chair Janet B Payeur/IA/APHIS/USDA

Meeting occurs in a different time zone (GMT-06:00) Central Time (US & Canada)
Time in the local time zone
When Starts Wed 06/23/2010 03:30 PM
Ends Wed 06/23/2010 04:30 PM 1 hour
Time in the Meeting time zone
Starts Wed 06/23/2010 02:30 PM
Ends Wed 06/23/2010 03:30 PM 1 hour

Where Location

Categorize

Invitees Required (to) Barbara A Kohn/MD/APHIS/USDA@USDA, (b)(6) @mbarqmail.com, Denise

Description

Denise Sofranko will discuss the first year of Stat Pak testing for TB in elephants. Kathy Connell - chair of USAHA TB committee- has asked subcommittee to make any recommendations for amending the current Elephant TB Guidelines.

Your Notes



Barbara A
Kohn/MD/APHIS/USDA
11/03/2010 12:33 PM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Sept 27 Feld incoming

Denise - here is this letter in case you don't have...

Barb



APHISletterSept27.2010.pdf



Barbara A
Kohn/MD/APHIS/USDA
11/03/2010 09:00 AM

To Denise M Sofranko/NM/APHIS/USDA
cc Kay A Carter-Corker/MD/APHIS/USDA@USDA, Nora E
Wineland/CO/APHIS/USDA@USDA
bcc
Subject Re: Stat-Pak testing procedures

Added some info in bullet 4 and current 2nd to last bullet. Put Chembio report results to licensee at 3rd to last....

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
11/03/2010 08:58 AM

To Barbara A Kohn/MD/APHIS/USDA
cc Kay A Carter-Corker/MD/APHIS/USDA@USDA, Nora E
Wineland/CO/APHIS/USDA@USDA
Subject Re: Stat-Pak testing procedures

No problem. I always welcome help.

I'm not seeing your changes though. I'll get some more coffee and look again.

thanks!

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

Barbara A Kohn---11/03/2010 06:53:46 AM---Thanks, Denise. Forgive me, but I edited a little - a



Barbara A
Kohn/MD/APHIS/USDA
11/03/2010 06:53 AM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc Kay A Carter-Corker/MD/APHIS/USDA@USDA, Nora E
Wineland/CO/APHIS/USDA@USDA
Subject Re: Stat-Pak testing procedures

Thanks, Denise.

Forgive me, but I edited a little - added and slight rearrange at the bottom... Is this OK?

Barb

[attachment "Procedures for Stat.docx" deleted by Denise M Sofranko/NM/APHIS/USDA]

Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA

To Barbara A Kohn/MD/APHIS/USDA, Nora E



11/03/2010 08:46 AM

Wineland/CO/APHIS/USDA@USDA, Kay A
Carter-Corker/MD/APHIS/USDA@USDA

cc

Subject Stat-Pak testing procedures

Hi all,

Just so we're all on the same page, I've attached a simple step by step doc. to outline the procedures we are using for Stat-Pak testing.

I thought we could use it if needed for our discussion this morning and we can make sure Chester has it as background for his USAHA presentation.

The bullet showing Chembio reporting to licensee/attending veterinarian is a recent addition and will be incorporated as soon as the testing team members and Chembio are notified of the change. The testing VMO will have to provide Chembio with contact information for reporting the test and Chembio will need to cc us on the results so we can complete the form.

[attachment "Procedures for Stat.docx" deleted by Barbara A Kohn/MD/APHIS/USDA]

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Barbara A
Kohn/MD/APHIS/USDA
11/03/2010 08:53 AM

To Denise M Sofranko/NM/APHIS/USDA
cc Kay A Carter-Corker/MD/APHIS/USDA@USDA, Nora E
Wineland/CO/APHIS/USDA@USDA
bcc
Subject Re: Stat-Pak testing procedures 

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Barb



Procedures for Stat.docx
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
11/03/2010 08:46 AM

To Barbara A Kohn/MD/APHIS/USDA, Nora E
Wineland/CO/APHIS/USDA@USDA, Kay A
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Just so we're all on the same page, I've attached a simple step by step doc. to outline the procedures we are using for Stat-Pak testing.

I thought we could use it if needed for our discussion this morning and we can make sure Chester has it as background for his USAHA presentation.

The bullet showing Chembio reporting to licensee/attending veterinarian is a recent addition and will be incorporated as soon as the testing team members and Chembio are notified of the change. The testing VMO will have to provide Chembio with contact information for reporting the test and Chembio will need to cc us on the results so we can complete the form.

[attachment "Procedures for Stat.docx" deleted by Barbara A Kohn/MD/APHIS/USDA]

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Barbara A
Kohn/MD/APHIS/USDA
10/29/2010 02:50 PM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: MAPIA testing - question

Denise -

I am not sure about what is being discussed exactly...I thought we had provided all the info and comments needed. I don't think Chembio is scheduled for the Tuesday cc - looks to be just APHIS. However, Kay should be scheduling a cc between the three of us and Chembio to discuss the issue separately. I think maybe we need the Tuesday info before we do.... Can you see my eye spinning!

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
10/29/2010 02:41 PM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject Re: MAPIA testing - question

Barb,

Thanks for the information. Is someone from Chembio going to be on the call on Tuesday?

I should probably give Konstantin a call to discuss so he has some more background.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

Barbara A Kohn---10/29/2010 12:01:07 PM---Denise - see the attachment at the bottom. Lila is c



Barbara A
Kohn/MD/APHIS/USDA
10/29/2010 12:01 PM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc
Subject Re: MAPIA testing - question

Denise - see the attachment at the bottom. Lila is our new FOIA specialist (a lawyer, but don't hold that against her!). I would assume from this that we could still have Chembio send the photos to you and have us protected from being forced to share them through FOIA (a win!). One of the many conference calls that are being scheduled next week will be one with Chembio to discuss results reporting. I still don't get why everyone is making this such a big issue. It has been explained to death already!

Have a good weekend. Talk with you on Monday!

Barb

----- Forwarded by Barbara A Kohn/MD/APHIS/USDA on 10/29/2010 01:58 PM -----



Lila



Kanovsky/MD/APHIS/USDA
10/29/2010 12:09 PM

To Chester A Gipson/MD/APHIS/USDA@USDA
cc Barbara.A.Kohn@aphis.usda.gov, Chester Gipson
<Chester.A.Gipson@usda.gov>,
Kay.A.Carter-Corker@aphis.usda.gov
Subject Re: MAPIA testing - question

Lila Kanovsky
FOIA Specialist
USDA-APHIS
Animal Care
4700 River Road, Unit 84
Riverdale, MD 20737
Phone: 301-734-0909; FAX: 301-734-4978
lila.kanovsky@aphis.usda.gov

From: Chester A Gipson/MD/APHIS/USDA
To: <Lila.Kanovsky@aphis.usda.gov>
Cc: Barbara.A.Kohn@aphis.usda.gov, Chester Gipson <Chester.A.Gipson@usda.gov>, Kay.A.Carter-Corker@aphis.usda.gov
Date: 10/22/2010 09:23 AM
Subject: Re: MAPIA testing - question

Those are the basic questions raised.
Thanks,
C. Gipson
301 734 4980

<Lila.Kanovsky@aphis.usda.gov>

10/22/2010 09:05 AM

To <Barbara.A.Kohn@aphis.usda.gov>, Chester Gipson <Chester.A.Gipson@usda.gov>
cc <Kay.A.Carter-Corker@aphis.usda.gov>
Subject MAPIA testing - question

I am writing up my research now. I'd like to be certain I've framed the issues correctly. Please check below and let me know if these are the questions you'd like answered and/or there are other questions I should be addressing.

ISSUES:

- 1) Are photos of MAPIA Gel tests performed by Chembio and housed at Chembio subject to a FOIA request?
- 2) Are photos of MAPIA Gel tests performed by Chembio and given to APHIS/Animal Care subject to a FOIA request?
- 3) If such photos can be subject to a FOIA request, may APHIS/Animal Care withhold them under a FOIA exemption?
- 4) May a facility use the FOIA process to receive results and/or photos of a MAPIA gel test, if that facility has not paid for the test?

Lila Kanovsky
FOIA Specialist

USDA-APHIS

Animal Care

4700 River Road, Unit 84

Riverdale, MD 20737

Phone: 301-734-0909; FAX: 301-734-4978

lila.kanovsky@aphis.usda.gov [attachment "MAPIA Gel Tests Memo.doc" deleted by Barbara A Kohn/MD/APHIS/USDA]



United States
Department of
Agriculture

Animal and Plant
Health Inspection
Service

4700 River Road
Riverdale, MD
20737

MEMORANDUM

TO: Chester Gipson
Barbara Kohn
Kay Carter-Corker

FROM: Lila Kanovsky

SUBJECT: Photos of MAPIA gels

ISSUES

- 1) Are photos of MAPIA Gels performed by Chembio and housed at Chembio subject to a FOIA request?
- 2) Are photos of MAPIA Gels performed by Chembio and given to APHIS/Animal Care subject to a FOIA request?
- 3) If such photos can be subject to a FOIA request, may APHIS/Animal Care withhold them under a FOIA exemption?
- 4) May a facility use the FOIA process to receive results and/or photos of MAPIRA gels, if that facility has not paid for the test?

SHORT ANSWERS

- 1) No. Photos of MAPIA gel tests performed by Chembio and not housed at APHIS are not "agency records" and cannot be subject to a FOIA request.
- 2) No. Although APHIS may possess some photos, the location of a record is just one factor in determining if it is an "agency record." Other factors weigh against the photo being an "agency record" and subject to FOIA.
- 3) Yes. FOIA exemption 4, which protects confidential commercial information, would allow us to withhold the photos from a FOIA requester.
- 4) No. Exemption 4 protects records when there is evidence that customers will utilize the FOIA as a substitute for directly purchasing the records.

ISSUE 1: Are photos of MAPIA Gel tests performed by Chembio and housed at Chembio subject to a FOIA request?

The Freedom of Information Act (FOIA) allows public access to federal agency records. "Records" are broadly defined to include any machine readable materials, regardless of format.¹ The photos of the MAPIA gel tests are records under the FOIA.

¹ Forsham v. Harris, 445 U.S. 169, 183 (1980) (quoting Records Disposal Act, 44 U.S.C. § 3301 (1980)).



Safeguarding American Agriculture

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An Equal Opportunity Provider and Employer

Federal Relay Service
(Voice/TTY/ASCII/Spanish)
1-800-877-8339

records,¹⁵ and the intent of the agency to retain control over the records and to use or dispose of them as they see fit.¹⁶ Here, all those factors weigh against finding the photos to be “agency records.” Besides from receiving copies of the results of the MAPIA tests (as a conduit for reporting to the licensee), APHIS has not exercised any supervision or control over the MAPIA tests. APHIS has not funded Chembio’s research, other than buying test kits from Chembio. APHIS has made no effort to “retain control” over the records. The photos at issue remain in control of Chembio, which continues to use them to further its own research and its own financial interests. APHIS has no authority to order to Chembio to dispose of the records.

Photos of MAPIA gel tests performed by Chembio and not housed at the USDA are not “agency records” and therefore cannot be subject to a FOIA request.

ISSUE 2: Are photos of MAPIA Gel tests performed by Chembio and given to APHIS/Animal Care subject to a FOIA request?

Although APHIS has obtained the agency records (the photos),¹⁷ the records must also be “under agency control at the time of the FOIA request.”¹⁸ Courts generally look at 4 factors to determine whether an agency has control of a record: (1) the intent of the documents creator to retain or relinquish control over the record; (2) the ability of the agency to use and dispose of the record as it sees fit; (3) the extent to which agency personnel have read or relied upon the document; and (4) the degree to which the document was integrated into the agency’s record systems or files.¹⁹

The photos of the MAPIA gels were created by Chembio for use in running their tests to determine whether an elephant is positive for the Mycobacterium TB complex. Chembio is continuing its research into this testing and has shown no intent to relinquish control of these photos to APHIS. APHIS does not generally receive the photos. Although APHIS personnel may review the photos, APHIS has no right to order Chembio to dispose of all the photos. APHIS personnel have not, as yet, relied in the photos in making any determinations. APHIS personnel have not integrated the photos into agency records systems or files. APHIS personnel’s use of MAPIA gel tests has been limited to the results provided by Chembio in the form of a +, -, or a number. This information has been provided to the facilities whose elephants were tested.

Photos of the MAPIA gel tests which APHIS has received are not “agency records” and therefore cannot be subject to a FOIA request.

ISSUE 3: If such photos can be subject to a FOIA request, may APHIS/Animal Care withhold them under a FOIA exemption?

The FOIA requires federal agencies to hand over all requested records unless an exemption applies.²⁰ Here, FOIA exemption 4 would allow APHIS to

¹⁵ *Hercules, Inc. v. Marsh*, 839 F.2d 1027, 1029 (4th Cir. 1988); *In Def of Animals v. NIH*, 543 F. Supp. 2d 83, 100-01 (D.D.C. 2008).

¹⁶ *Los Alamos Study Group v. DOE*, No. 97-1412, slip op. at 4 (D.N.M. July 22, 1998); *Tax Analysts v. DOJ*, 913 F. Supp. 599, 607 (D.D.C. 1996).

¹⁷ The first part of the test articulated in *DOJ v. Tax Analysts*, 492 U.S. 136, 144-45 (1989).

¹⁸ The second part of the test articulated in *DOJ v. Tax Analysts*, *Id.*

¹⁹ *E.g. Burka v. HHS*, 87 F.3d 508, 515 (D.C. Cir. 1996).

²⁰ 5 U.S.C. § 552 (2006) as amended by Pub. L. No. 110-175, 121 stat. 2524.

withhold the photos. Exemption 4 provides that FOIA does not apply to matters that are “trade secrets and commercial or financial information obtained from a person and privileged or confidential.”²¹

The D.C. Circuit has limited “trade secret” to information that relates directly to the production process.²² It is unlikely that a photo of the MAPIA gel test would fall within this narrow definition. “Commercial” information includes anything compiled in pursuit of profit, including research data.²³ The MAPIA gel test was created by Chembio for profit; photos of the MAPIA gels would be commercial.²⁴

The commercial information must be obtained from a person. The definition of “person” includes anyone other than the federal government, including corporations, so Chembio would fit this definition.²⁵ The commercial information must also be “privileged or confidential.” Privilege under the FOIA is limited to those privileges found in litigation, and would not apply here.

In determining whether commercial information is “confidential,” The D.C. distinguished between compelled submission of information (i.e. information required to apply for a license), and voluntary submission of information (i.e. the government has no legal authority to obtain the records).²⁶ When information is voluntarily submitted, it is categorically protected if it is not customarily disclosed to the public at large by the submitter.²⁷

Here, the photos of the MAPIA gels were submitted voluntarily. Chembio has voluntarily shared the results of the MAPIA gel tests with APHIS to facilitate better communication with facilities receiving the results. Because submission is voluntary, we only need look at Chembio’s customary treatment of the photos of MAPIA gel tests. Chembio does not give photos of the MAPIA gel tests to the public at large. That is sufficient to withhold the photos under Exemption 4 of the FOIA.

ISSUE 4: May a facility use the FOIA process to receive results and/or photos of MAPIA gels, if that facility has not paid for the test?

No. Exemption 4 also protects records when there is evidence that customers will utilize the FOIA as a substitute for directly purchasing the records.²⁸ Here, Feld Entertainment will not be able to use the FOIA to obtain unpaid photos or results of their MAPIA gel tests because to allow them to do so, would circumvent their need to pay for the records.

²¹ *Id.* at (b)(4).

²² *Pub. Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C. Cir. 1983).

²³ *See Wash Post Co. v. HHS.*, 690 F.2d 252, 266 (D.C. Cir. 1982).

²⁴ There is one case where information submitted by a scientist in connection with a grant application was not deemed “commercial” because the court held that a “a noncommercial scientist’s research design is not literally a trade secret or item of commercial information, for it defies common sense to pretend that the scientist is engaged in trade or commerce.” *Wash. Research Project, Inc. v. HEW*, 504 F.2d 238, 244 (D.C. Cir. 1974) (reverse FOIA lawsuit ???). However, there is no question that Chembio is a for-profit entity, hence this case does not apply.

²⁵ *See e.g. Nadler v. FDIC*, 92 F.3d 93, 95 (2d Cir. 1996).

²⁶ *Critical Mass Energy Project v. NRC*, 975 F.2d 871 (D.C. Cir. 1992).

²⁷ *Id.* at 879. In the case of information that is compelled to be submitted, the D.C. Circuit has held that commercial information is confidential if its disclosure could either impair the government’s ability to obtain that information in the future or it could cause substantial competitive harm to the submitter of the information. *Id.* at 880; FOIA Update Vol. XIV, No. 2 1993

²⁸ *See Cody Zeigler Inc. v. U.S. Dep’t of Labor*, No. C2-00-134, 2002 WL 31159309.



Barbara A
Kohn/MD/APHIS/USDA
10/29/2010 02:01 PM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: MAPIA testing - question

Denise - see the attachment at the bottom. Lila is our new FOIA specialist (a lawyer, but don't hold that against her!). I would assume from this that we could still have Chembio send the photos to you and have us protected from being forced to share them through FOIA (a win!). One of the many conference calls that are being scheduled next week will be one with Chembio to discuss results reporting. I still don't get why everyone is making this such a big issue. It has been explained to death already!

Have a good weekend. Talk with you on Monday!

Barb

----- Forwarded by Barbara A Kohn/MD/APHIS/USDA on 10/29/2010 01:58 PM -----



Lila
Kanovsky/MD/APHIS/USDA
10/29/2010 12:09 PM

To Chester A Gipson/MD/APHIS/USDA@USDA
cc Barbara.A.Kohn@aphis.usda.gov, Chester Gipson
<Chester.A.Gipson@usda.gov>,
Kay.A.Carter-Corker@aphis.usda.gov
Subject Re: MAPIA testing - question

Lila Kanovsky
FOIA Specialist
USDA-APHIS
Animal Care
4700 River Road, Unit 84
Riverdale, MD 20737
Phone: 301-734-0909; FAX: 301-734-4978
lila.kanovsky@aphis.usda.gov

From: Chester A Gipson/MD/APHIS/USDA
To: <Lila.Kanovsky@aphis.usda.gov>
Cc: Barbara.A.Kohn@aphis.usda.gov, Chester Gipson <Chester.A.Gipson@usda.gov>, Kay.A.Carter-Corker@aphis.usda.gov
Date: 10/22/2010 09:23 AM
Subject: Re: MAPIA testing - question

Those are the basic questions raised.

Thanks,
C. Gipson
301 734 4980

<Lila.Kanovsky@aphis.usda.gov>

10/22/2010 09:05 AM

To <Barbara.A.Kohn@aphis.usda.gov>, Chester Gipson <Chester.A.Gipson@usda.gov>
cc <Kay.A.Carter-Corker@aphis.usda.gov>
Subject MAPIA testing - question

I am writing up my research now. I'd like to be certain I've framed the issues correctly. Please check below and let me know if these are the questions you'd like answered and/or there are other questions I should be addressing.

ISSUES:

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- 4) May a facility use the FOIA process to receive results and/or photos of a MAPIA gel test, if that facility has not paid for the test?

Lila Kanovsky
FOIA Specialist
USDA-APHIS
Animal Care
4700 River Road, Unit 84
Riverdale, MD 20737
Phone: 301-734-0909; FAX: 301-734-4978



lila.kanovsky@aphis.usda.gov MAPIA Gel Tests Memo.doc

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

Barbara A Kohn---10/21/2010 12:36:03 PM---Denise and Nora - Here is the first shot at this part



Barbara A
Kohn/MD/APHIS/USDA
10/21/2010 12:36 PM

To Denise M Sofranko/NM/APHIS/USDA@USDA, Nora E
Wineland/CO/APHIS/USDA@USDA
cc

Subject Talking points on TB testing review

Denise and Nora -

Here is the first shot at this part. May to organize differently. Tired to keep it simple and direct.

Looking forward to all comments and corrections.

Barb

Review of Elephant TB testing program

Official testing began in March 2010

First year testing will end in March 2011

- Current reporting of results is done by ~~goes through~~ APHIS
 - Stat Pak – APHIS on site or through NVSL
 - MAPIA – Chembio send results to APHIS, APHIS delivers to licensees
- On-site testing
 - APHIS ensures positive ID of all animals tested
 - APHIS certified veterinarian must run Stat-Pak test
 - APHIS ensures chain of custody of samples when sent for MAPIA testing
 - Results report ~~sheet~~ left with licensee (attending veterinarian)
 - Trunk washes should be done at same time (within two ~~the same~~ week of blood testing)
- MAPIA
 - APHIS ensures sample ID on blood sent for MAPIA test
 - Chembio runs the test
 - Results sent to APHIS
 - APHIS completes report ~~result table~~ and gives to attending veterinarian

APHIS stated we would review the program at the end of the first year. The USAHA sub committee of the TB Committee requested periodic updates on testing progress and we are supply them with confidential results with facility and elephant identifiers removed. Protocols are being modified ~~tweaked~~ as needed while we work through the first year.

- Review process:

- APHIS review panel will include subject matter experts, field inspectors (TB testing team member(s)), program analyst, management team representative.
- Input will be obtained from APHIS personnel, licensees, public, and animal concern groups and laboratory organizations as needed. Should Chembio be added to the list?
- The process will start in January 2011, and be completed by March 2011. All interested parties will be advised of any changes in the current protocols and policies as that time.
- Topics to be addressed:
 - Reporting of results
 - Chain of custody/positive animal ID issues
 - Licensing restrictions of the test kits
 - Any changes in guidelines as approved by USAHA
- Cannot be fully reviewed until more tests, especially traveling elephants, have been completed. Most travelling elephants will be tested during the traditional "winter" season when many return to their home facilities.
-
- Current testing statistics:

1994- 2010

50 confirmed cases (by culture) of MTb complex

46 Asian MTb, 3 African MTb, 1 African M.bovis

31/50 diagnosed antemortem; 19 at necropsy

Majority of elephants did NOT show clinical signs suggestive of TB.

Approximately 454 elephants in U.S. licensed facilities
Stat-Pak results reported as of October 8:

209 Tested

19 Not tested (young, in musth, not able to handle)

226 Scheduled by March 2011

173 Stat-Pak non reactive

38 Stat-Pak reactive

19 MAPIA reactive and indicative of MTb



Barbara A
Kohn/MD/APHIS/USDA
10/20/2010 07:56 AM

To Denise M Sofranko/NM/APHIS/USDA
cc Nora E Wineland/CO/APHIS/USDA@USDA
bcc
Subject Re: Questions/comments from Cindy Smith

Nora and Denise -

I, too, should be available anytime on Thursday (before 4 PM EDT)....Thanks.

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
10/19/2010 10:49 PM

To Nora E Wineland/CO/APHIS/USDA@USDA
cc Barbara A Kohn/MD/APHIS/USDA@USDA
Subject Re: Questions/comments from Cindy Smith

Hi Nora,
I imagine I'll be busy catching but will be available at your convenience. Anytime after 7 mountain time. I think our call with Ray is friday.
Just let me know what works best for you two.
Thanks!

Nora E Wineland---10/19/2010 06:44 AM MDT---

From: Nora E Wineland
To: Denise Sofranko
Cc: Barbara Kohn
Date: 10/19/2010 06:44 AM MDT
Subject: Re: Questions/comments from Cindy Smith

Denise --- Barb and I were on the call yesterday regarding how we will proceed to answer all of these questions. What does your Thursday look like for a call to catch up on things?? I am available at 9 am eastern time, or after 12:30 eastern. Let me know what will work on your end. Barb -- please do the same and let me know what times work for you.

Thanks,

Nora

Nora E Wineland, DVM MS DACVPM
Director, Center for Animal Welfare
USDA-APHIS-AC
6501 Beacon Drive
Kansas City, MO 64141
816-926-2130

Denise M Sofranko---10/18/2010 01:00:22 PM---Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
10/18/2010 01:00 PM

To Chester A Gipson/MD/APHIS/USDA@USDA
cc Allan T Hogue/MD/APHIS/USDA@USDA, Andrea M
Morgan/MD/APHIS/USDA@USDA, Barbara A
Kohn/MD/APHIS/USDA@USDA, Betty J
Goldentyer/NC/APHIS/USDA@USDA, James M
Tuck/MD/APHIS/USDA@USDA, Kay A
Carter-Corker/MD/APHIS/USDA@USDA, Nora E
Wineland/CO/APHIS/USDA@USDA, Robert M
Gibbens/CO/APHIS/USDA@USDA, Thay
Ly/MD/APHIS/USDA@USDA, Yvette D
Joyner/MD/APHIS/USDA@USDA
Subject Re: Questions/comments from Cindy Smith 

Hi all,

I'm still on leave but checking in from time to time. I'll be back in my office on Thursday.

I will review and answer more of the attached questions if necessary when I'm back but I want to be very clear about one of them in particular.

As far as I know no one from AC has ever required that an elephant be treated on the basis of a MAPIA test. I have been telling people just the opposite. We are not making people treat elephants. There is a provision in the Guidelines for prophylactic treatment but that is a decision to be made by the attending veterinarian. This decision should be made on the basis of many factors, including age and medical condition of the elephant and exposure history.

We have put some attending veterinarians in touch with experts in this area to discuss but in the Dickerson Park case, the experts were consulted after treatment had been started.

I don't know how this rumor got started and I only know of the one case in Missouri (Dickerson Park). I don't know anything about the other states that are referenced in the questions.

I was also asked to answer a similar list of questions by ^{(b)(6)}  on behalf of the EMA board when I was at the meeting earlier this month.

Thanks!

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

Chester A Gipson---10/18/2010 09:09:39 AM---Attached are questions/comments prepared by ti

Chester A
Gipson/MD/APHIS/USDA
10/18/2010 09:09 AM

To Kay A Carter-Corker/MD/APHIS/USDA@USDA, Robert M
Gibbens/CO/APHIS/USDA@USDA, Betty J
Goldentyer/NC/APHIS/USDA@USDA, Allan T
Hogue/MD/APHIS/USDA@USDA, Thay
Ly/MD/APHIS/USDA@USDA, Nora E
Wineland/CO/APHIS/USDA@USDA, Yvette D
Joyner/MD/APHIS/USDA@USDA, Andrea M
Morgan/MD/APHIS/USDA@USDA, James M
Tuck/MD/APHIS/USDA@USDA, Barbara A
Kohn/MD/APHIS/USDA@USDA, Denise M
Sofranko/NM/APHIS/USDA@USDA

cc

Subject Questions/comments from Cindy Smith

Attached are questions/comments prepared by the administrator from the meeting she attended with ringling representatives and the Office of the Secretary. The scanner was disoriented:>).

Thanks,

C. Gipson

301 734 4980

[attachment "Cindy TB Questions.pdf" deleted by Denise M Sofranko/NM/APHIS/USDA]



Barbara A
Kohn/MD/APHIS/USDA
10/15/2010 01:46 PM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: Fw: Feld Entertainment

Yes, I saw this record....found out about the meeting only after the fact (as we discussed). Wish someone would just say no!

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
10/15/2010 01:26 PM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject Fw: Feld Entertainment

fyi

So many factual inaccuracies, I don't even know where to begin.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

----- Forwarded by Denise M Sofranko/NM/APHIS/USDA on 10/15/2010 11:18 AM -----



"Holt, Thomas"
<holtt@doacs.state.fl.us>
10/15/2010 06:28 AM

To <Gregory.S.Gaj@aphis.usda.gov>,
<Denise.M.Sofranko@aphis.usda.gov>
cc "Lamb, Sam" <lamb@doacs.state.fl.us>, "Jeter, Bill"
<jeterw@doacs.state.fl.us>
Subject FW: Feld Entertainment

You have probably already received a copy of this letter but am sending in case you have not.

Thomas Holt, D.V.M.
State Veterinarian/Director
Division of Animal Industry
Florida Department of Agriculture and Consumer Services
Phone: (850) 410-0900
Fax: (850) 410-0915
E-mail: holtt@doacs.state.fl.us
Web Site: www.doacs.state.fl.us/ai

From: (b)(6)@verizon.net]
Sent: Thursday, October 14, 2010 4:52 PM
To: Holt, Thomas (b)(6)
Cc: (b)(6)

Subject: Feld Entertainment

Dr. Holt:

I wanted to share with you the attached letter from Feld Entertainment to APHIS Administrator Cindy Smith. Earlier this week, Feld representatives did meet with Administrator Smith and UnderSecretary John Ferrell to discuss, among other things, the request by Feld to receive the test results from the Chembio Lab

As you know, we continue to have issues with the application of the test and with some aspects of the guidelines. We will keep you apprised of our ongoing discussions with USDA and hope that you will not hesitate to contact us if you have any questions.

Regards,

(b)(6)

(b)(6)

Kelley Drye & Warren LLP

Washington Harbour, Suite 400

3050 K Street, NW, Washington, DC 20007-5108

202.342 (b)(6) @kelleydrye.com

www.kelleydrye.com[attachment "APHISletterSept27.2010.pdf" deleted by Barbara A Kohn/MD/APHIS/USDA]



Barbara A
Kohn/MD/APHIS/USDA
09/29/2010 08:06 AM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: Fw: MAPIA TESTING

Aren't they special?
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
09/28/2010 06:31 PM

To Betty J Goldentyer/NC/APHIS/USDA@USDA, Gregory S
Gaj/FL/APHIS/USDA@USDA, Barbara A
Kohn/MD/APHIS/USDA
cc
Subject Fw: MAPIA TESTING

fyi

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

----- Forwarded by Denise M Sofranko/NM/APHIS/USDA on 09/28/2010 04:31 PM -----



(b)(6)
(b)(6) @feldinc.com>
09/28/2010 03:09 PM

To (b)(6)@feldinc.com>
cc (b)(6)@feldinc.com>, (b)(6)
(b)(6)@feldinc.com>,
"Denise.M.Sofranko@aphis.usda.gov".
<Denise.M.Sofranko@aphis.usda.gov>
Subject FW: MAPIA TESTING

(b)(6)

(b)(6) forwarded to me the email below regarding an invoice for our sample and asked me to respond.

As you are aware, we have requested a copy from Chembio of the actual test results from the samples previously taken from our elephants and submitted by USDA. You informed me yesterday that Chembio's position is that it will not provide us with the actual test results, that Chembio has no obligation to release results to owners of samples received from USDA, and that all such samples are the property of Chembio. You further stated that Chembio has complied with its arrangement with USDA by reporting the outcome of the tests thereto.

We disagree with, and do not consent to, Chembio's position. Any samples submitted from Feld Entertainment's animals are the property of Feld Entertainment, and may not be tested or used in any way without our express permission. This will serve as our written request that Chembio immediately

return our samples to us.

Given Chembio's position regarding its refusal to release test results to us, we will not be paying the invoice referenced below or any others until this matter is resolved in a manner satisfactory to us. Until then, we suggest that Chembio seek payment from USDA under the referenced arrangement upon which Chembio is relying. I would appreciate it if you would relay this information to (b)(6)

I have copied Dr. Sofranko from the USDA, as well as our legal counsel (b)(6) Any further communications should be directed to them.

(b)(6)

(b)(6)

Government Relations
Feld Entertainment, Inc.
8607 Westwood Center Drive
Vienna, VA 22182

www.feldentertainment.com

www.ringling.com

www.elephantcenter.com

From: (b)(6)
Sent: Tuesday, September 28, 2010 11:15 AM
To: Albert, Thomas
Subject: FW: MAPIA TESTING

(b)(6)

Ringling Bros. and Barnum & Bailey Center for Elephant Conservation
Ringling Bros. and Barnum & Bailey Circus

From: (b)(6) [mailto:(b)(6)@chembio.com]
Sent: Tuesday, September 28, 2010 10:35 AM
To: (b)(6)
Subject: RE: MAPIA TESTING
Dear Ellen,

I have not had a response from my earlier e-mails. Should I invoice the 500.00 as I did before, or would you like to pay this MAPIA (for RAJA) by credit card? Please let me know so that I can give R&D the go ahead for the results.

If you have any questions, please let me know.

Regards,

(b)(6)



(b)(6)@chembio.com
631-924-1135 (b)(6)
631-924-6033 Fax

From: (b)(6)
Sent: Tuesday, September 21, 2010 9:51 AM
To: (b)(6)
Subject: RE: MAPIA TESTING

Dear (b)(6)

Can you please let me know if I should invoice as before? Can you also verify payment type?

Thank you,

(b)(6)



(b)(6)@chembio.com
631-924-1135 (b)(6)
631-924-6033 Fax

From: (b)(6)
Sent: Wednesday, September 15, 2010 11:34 AM
To: (b)(6)
Subject: RE: MAPIA TESTING

Good Morning (b)(6)

We have received a sample from Dr. Greg Gaj for RAJA for MAPIA testing. **Should I invoice as before?** Invoice will be \$500.00 for the R&D Testing; and, results will not be released until payment is made. Let me know if there is anything additional I need to do.

Thanks,

(b)(6)



(b)(6)@chembio.com
631-924-1135 (b)(6)
631-924-6033 Fax

From: (b)(6)@feldinc.com]
Sent: Wednesday, August 04, 2010 6:03 PM
To: (b)(6)
Subject: W-9 form

Hi (b)(6)

Please sign the attached form and return it to me so that we can process the Chembio invoice.

Thanks,

(b)(6)

(b)(6)

Ringling Bros. and Barnum & Bailey Center for Elephant Conservation
Ringling Bros. and Barnum & Bailey Circus



Barbara A
Kohn/MD/APHIS/USDA
09/21/2010 12:00 PM

To Denise M Sofranko/NM/APHIS/USDA
cc Abbey L Shaffer/MD/APHIS/USDA@USDA, Andrea M Morgan/MD/APHIS/USDA@USDA, kay.a.carter-corker@aphis.usda.gov
bcc
Subject Re: Info request from Budget that may lead to a Congressional Briefing - you guessed - Elephant TB

Not according to Karen, but they/he didn't ask any budget questions - just the one on the procedures.

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
09/21/2010 11:59 AM

To Barbara A Kohn/MD/APHIS/USDA
cc Abbey L Shaffer/MD/APHIS/USDA@USDA, Andrea M Morgan/MD/APHIS/USDA@USDA, kay.a.carter-corker@aphis.usda.gov
Subject Re: Info request from Budget that may lead to a Congressional Briefing - you guessed - Elephant TB

Do you think they are questioning the resources we are putting into the testing and related actions?

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

Barbara A Kohn---09/21/2010 09:34:41 AM---Kay and Andy - A heads up! Yesterday while I was



Barbara A
Kohn/MD/APHIS/USDA
09/21/2010 09:34 AM

To kay.a.carter-corker@aphis.usda.gov, Andrea M Morgan/MD/APHIS/USDA@USDA, Denise M Sofranko/NM/APHIS/USDA@USDA
cc Abbey L Shaffer/MD/APHIS/USDA@USDA
Subject Info request from Budget that may lead to a Congressional Briefing - you guessed - Elephant TB

Kay and Andy -

A heads up! Yesterday while I was furiously typing the briefing memo draft for the Ringling meeting for Cindy, I was told of a call from Karen in Budget...as I couldn't talk yesterday, Clea took the info and I returned the call this AM. Budget has received a very vague "out of the blue" request from the Staff of one of the Appropriations senator (or may representative) - don't know which one - about what the elephant TB testing protocol is.

So, I tried to give Karen Ranzo the streamlined version this AM and, as you all know, it can get complicated (History, guidelines, changes, etc.) She had tried to review the 2008 guidelines, but as she was not familiar with the tests, was in need of info. After our long discussion, she recommended that we talk directly (conference call)(to the staffer...I said we would need to go through Congressional Relations (LPA) - Abbey Shaffer - and that we would be more than willing to participate in a briefing. Looks like we will be explaining the program at least one more time!



Barbara A
Kohn/MD/APHIS/USDA
09/14/2010 12:55 PM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc
bcc
Subject Re: Fw: Use of Accredited Vets for elephant TB testing

Just got into Houston (only here for the session this PM, so I don't know! Will head downtown soon.

Barb

Denise M Sofranko---09/14/2010 12:51 PM EDT---

From: Denise M Sofranko
To: Barbara Kohn
Cc: Andrea Morgan; Kay Carter-Corker; Nora Wineland
Date: 09/14/2010 12:51 PM EDT
Subject: Re: Fw: Use of Accredited Vets for elephant TB testing

Thanks!

How is AZA going?

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

Barbara A Kohn---09/14/2010 10:46:16 AM---Denise - will be glad to work with you when I get b:



Barbara A
Kohn/MD/APHIS/USDA
09/14/2010 10:46 AM

To Denise M Sofranko/NM/APHIS/USDA@USDA, Kay A
Carter-Corker/MD/APHIS/USDA@USDA
cc Andrea M Morgan/MD/APHIS/USDA@USDA, Nora E
Wineland/CO/APHIS/USDA@USDA
Subject Re: Fw: Use of Accredited Vets for elephant TB testing

Denise - will be glad to work with you when I get back to "the office" on Thursday. Thanks for digging out the original documents.

Barb

Denise M Sofranko---09/14/2010 11:45 AM EDT---

Kay A Carter-Corker---09/14/2010 09:31:27 AM---Denise and Barb, would one or both of you dr:



Barbara A
Kohn/MD/APHIS/USDA
09/14/2010 12:46 PM

To Denise M Sofranko/NM/APHIS/USDA@USDA, Kay A
Carter-Corker/MD/APHIS/USDA@USDA
cc Andrea M Morgan/MD/APHIS/USDA@USDA, Nora E
Wineland/CO/APHIS/USDA@USDA

bcc

Subject Re: Fw: Use of Accredited Vets for elephant TB testing

Denise - will be glad to work with you when I get back to "the office" on Thursday. Thanks for digging out the original documents.

Barb

Denise M Sofranko---09/14/2010 11:45 AM EDT---

From: Denise M Sofranko
To: Kay Carter-Corker
Cc: Andrea Morgan; Barbara Kohn; Nora Wineland
Date: 09/14/2010 11:45 AM EDT
Subject: Re: Fw: Use of Accredited Vets for elephant TB testing

I'll work on an SOP but I've also attached some documents to provide some history. The StatPakissue doc. was the result of meetings with VS, including Regional Epidemiologists, NVSL TB lab personnel, CVB and ARS. The test approval letter followed the issues doc. after more discussion between AC and VS.

[attachment "elephant test approval ltr.pdf" deleted by Barbara A Kohn/MD/APHIS/USDA]
[attachment "Statpakissue430.doc" deleted by Barbara A Kohn/MD/APHIS/USDA]
[attachment "5954025-Signed Copy[1].pdf" deleted by Barbara A Kohn/MD/APHIS/USDA]

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

Kay A Carter-Corker---09/14/2010 09:31:27 AM---Denise and Barb, would one or both of you dr:



Kay A
Carter-Corker/MD/APHIS/US
DA
09/14/2010 09:31 AM

To Barbara A Kohn/MD/APHIS/USDA@USDA, Denise M
Sofranko/NM/APHIS/USDA@USDA
cc Nora E Wineland/CO/APHIS/USDA@USDA, Andrea M
Morgan/MD/APHIS/USDA@USDA
Subject Fw: Use of Accredited Vets for elephant TB testing

Denise and Barb, would one or both of you draft a formal SOP that describes how accredited vets can be involved in the elephant TB testing protocol?

Sincerely

Kay A. Carter-Corker, D.V.M.
Assistant Deputy Administrator
Animal Care
4700 River Road, Suite 6D-03E
Riverdale, MD 20737

(301) 734-6328 (office)
(301) 734-4978 (Fax)

----- Forwarded by Kay A Carter-Corker/MD/APHIS/USDA on 09/14/2010 11:24 AM -----

**Chester A
Gipson/MD/APHIS/USDA**
07/26/2010 11:47 AM

To Kay A Carter-Corker/MD/APHIS/USDA@USDA
cc Andrea M Morgan/MD/APHIS/USDA@USDA, Barbara A
Kohn/MD/APHIS/USDA@USDA, Denise M
Sofranko/NM/APHIS/USDA@USDA
Subject Re: Use of Accredited Vets for elephant TB testing 

Thanks Kay. I think this needs to be prepared as a protocol re the subject with the understanding the accredited Vets should have experience working with elephants which was discussed initially as the screen out factor. No desire for blanket approval for any accredited vet.

C. Gipson
301 734 4980

Kay A Carter-Corker---07/26/2010 10:10:55 AM---Chester, you requested information on the use



Barbara A
Kohn/MD/APHIS/USDA
06/09/2010 12:48 PM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: Fw: Elephant Stat-Pak testing results -

Thanks - I would like to be present if the time is agreeable...Don't know how many time zones are involved. Only day I cannot make it at all is Friday the 18th (kids graduate from 8th grade). Have meeting from 10-2 on the 16th and the 22nd. Other dates should be OK for me. If those times are preferred by others, that's OK too...I can get info from you!

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
06/09/2010 12:38 PM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject Fw: Elephant Stat-Pak testing results -

FYI, Do you want to be on this call too?

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

----- Forwarded by Denise M Sofranko/NM/APHIS/USDA on 06/09/2010 10:37 AM -----



Janet B
Payeur/IA/APHIS/USDA
06/08/2010 04:54 PM

To (b)(6)@palmbeachzoo.org>, rwaters@nadc.ars.usda.gov, (b)(6)@embarqmail.com, Kathy A Orloski/CO/APHIS/USDA@USDA
cc (b)(6)@elephantcare.org, Denise M Sofranko@aphis.usda.gov, (b)(6)@msn.com
Subject Elephant Stat-Pak testing results -

TB Elephant Subcommittee

I have been asked by (b)(6) to reconvene the Elephant TB subcommittee and review the results of the first year of testing with the Elephant Stat-Pak. Dr Denise Sofranko has offered to send me the data for our review. She would like us to review some of the different scenarios that have happened this last year ie. Trunk positive/Stat Pak non-reactive etc which might result in a modification of the TB Elephant Guidelines.

(b)(6) we would like your input if possible, since you have been doing alot of work in Nepal and may have some advice for us.

Please look on your calendar and give me your availability for a conference call next week - week of June

13 and the week of June 20.

Janet B. Payeur DVM, MPH, PhD
Scientific Outreach Coordinator
National Veterinary Services Laboratories
1920 Dayton Avenue
Ames, IA 50010

515-337-7003

Fax 515-337-7397

E-mail: Janet.B.Payeur@aphis.usda.gov



Barbara A
Kohn/MD/APHIS/USDA
04/22/2010 11:58 AM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Letter to sent to State Vets regarding StatPak test results

Denise - attached is a file of the draft for the letter we can use to State vets for reporting the test results. If/when we report MAPIA, I can manually change the sentence in paragraph 1.

Is this what you had in mind?

Barb



State Vet Report letter template.docx



United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

4700 River Road
Unit 84
Riverdale, MD
20737

Dear Dr.,

USDA, APHIS, Animal Care has recently conducted official testing for elephant tuberculosis at the facilities in your state identified in the attached table(s). The results of the Elephant TB Stat-Pak® testing are included in the table. Any reactive samples have been sent on to Chembio Diagnostic, Inc., for further MAPIA testing. When those results are available, we will send them to your office.

Please feel free to contact me (301-734-7833) or Dr. Denise Sofranko (240-461-9142) if there are any questions or concerns about the tests. Thank you for your continued cooperation in this testing and monitoring program.

Sincerely,

Barbara Kohn
Senior Staff Veterinarian
Animal Care





Barbara A
Kohn/MD/APHIS/USDA
04/19/2010 04:30 PM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc
bcc
Subject Re: NJ state vet

I get it! Must have misread the table and had brain freeze. I will let NJ know closer to the test who is carrying them.

Having fun yet? Could be here doing Queenie calls!

Barb
Denise M Sofranko

----- Original Message -----

From: Denise M Sofranko
Sent: 04/19/2010 02:27 PM MDT
To: Barbara Kohn
Subject: Re: NJ state vet

(b)(6) is not a VMO so she won't be doing that but she is the inspector for NJ.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

Barbara A Kohn---04/19/2010 02:26:30 PM---I thought it would be (b)(6) but the list of elephant



Barbara A
Kohn/MD/APHIS/USDA
04/19/2010 02:26 PM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc
Subject Re: NJ state vet

I thought it would be (b)(6) it the list of elephant facilities said (b)(6)

Anyway, they just want the name of the person who is bring the test into their state.

Barb
Denise M Sofranko

----- Original Message -----

From: Denise M Sofranko
Sent: 04/19/2010 02:22 PM MDT
To: Barbara Kohn
Subject: NJ state vet

Hey Barb,

No problem with notifying NJ about reactive Stat-Paks with MAPIA positives but do we need to send VMO names? Obviously (b)(6) won't be doing the testing in NJ.

I'll have to see who is assigned there but I think it's probabl (b)(6)

Denise M. Sofranko, DVM
Field Specialist for Elephants

USDA/APHIS/Animal Care



Barbara A
Kohn/MD/APHIS/USDA
04/19/2010 04:26 PM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc
bcc
Subject Re: NJ state vet

I thought it would be (b)(6) but the list of elephant facilities said (b)(6)

Anyway, they just want the name of the person who is bring the test into their state.

Barb
Denise M Sofranko

----- Original Message -----

From: Denise M Sofranko
Sent: 04/19/2010 02:22 PM MDT
To: Barbara Kohn
Subject: NJ state vet

Hey Barb,

No problem with notifying NJ about reactive Stat-Paks with MAPIA positives but do we need to send VMO names? Obviously, (b)(6) on't be doing the testing in NJ.

I'll have to see who is assigned there but I think it's probably (b)(6)

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

Barb



Barbara A
Kohn/MD/APHIS/USDA
09/17/2010 09:34 AM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc

Subject Re: Fw: USDA-APHIS-AC request for poster/presentation on TN TB in elephants investigation

Thanks, Denise.... Pretty general but the bar graph is very helpful...

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
09/17/2010 09:25 AM

To Barbara A Kohn/MD/APHIS/USDA
cc

Subject Fw: USDA-APHIS-AC request for poster/presentation on TN TB in elephants investigation

fyi

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

----- Forwarded by Denise M Sofranko/NM/APHIS/USDA on 09/17/2010 07:24 AM -----



Nora E
Wineland/CO/APHIS/USDA
09/17/2010 07:19 AM

To Chester A Gipson/MD/APHIS/USDA@USDA, Andrea M Morgan/MD/APHIS/USDA@USDA, James M Tuck/MD/APHIS/USDA@USDA, Kay A Carter-Corker/MD/APHIS/USDA@USDA, Yvette D Joyner/MD/APHIS/USDA@USDA, Robert M Gibbens/CO/APHIS/USDA@USDA, Betty J Goldentyer/NC/APHIS/USDA@USDA, Nora E Wineland/CO/APHIS/USDA@USDA, Allan T Hogue/MD/APHIS/USDA@USDA, Denise M Sofranko/NM/APHIS/USDA@USDA

cc

Subject Fw: USDA-APHIS-AC request for poster/presentation on TN TB in elephants investigation

see below for the powerpoint that Nina Marano presented re the elephants in TN

Nora E Wineland, DVM MS DACVPM
Director, Center for Animal Welfare
USDA-APHIS-AC
6501 Beacon Drive
Kansas City, MO 64141
816-926-2130

----- Forwarded by Nora E Wineland/CO/APHIS/USDA on 09/17/2010 08:17 AM -----



"Gomez, Thomas M.
(CDC/OID/NCZVED)"
<tmg1@cdc.gov>
09/16/2010 03:19 PM

To "Murphree, Rendi (CDC tn.gov (CDC tn.gov))"
<rendi.murphree@tn.gov>, "Marano, Nina
(CDC/OID/NCPDCID)" <nbm8@CDC.GOV>,
Nora.E.Wineland@aphis.usda.gov
cc "Gomez, Thomas M. (CDC/OID/NCZVED)"
<tmg1@CDC.GOV>
Subject RE: USDA-APHIS-AC request for poster/presentation on TN
TB in elephants investigation

Thanks again Rendi and Nina.

I've included Nora on this posting for her follow-up with you if needed regarding the poster and discussant PPT.

Tom G.

From: Murphree, Rendi (CDC tn.gov (CDC tn.gov))
Sent: Wednesday, September 15, 2010 5:50 PM
To: Marano, Nina (CDC/OID/NCPDCID); Gomez, Thomas M. (CDC/OID/NCZVED)
Subject: RE: USDA-APHIS-AC request for poster/presentation on TN TB in elephants investigation

Poster attached. Enjoy!

Rendi Murphree, PhD
CDR, USPHS
CDC Epidemic Intelligence Service Officer
Tennessee Department of Health
Communicable and Environmental Disease Services
1st Floor, Cordell Hull Building
425 5th Avenue North
Nashville, TN 37243
615-741-7247
615-741-3857 (fax)
rendi.murphree@tn.gov
rmurphree@cdc.gov

>>>

From: "Gomez, Thomas M. (CDC/OID/NCZVED)" <tmg1@cdc.gov>
To: "Marano, Nina (CDC/OID/NCPDCID)" <nbm8@CDC.GOV>
Date: 9/15/2010 6:42 AM
Subject: RE: USDA-APHIS-AC request for poster/presentation on TN TB in elephants investigation
CC: "Murphree, Rendi (CDC tn.gov (CDC tn.gov))" <rendi.murphree@tn.gov>

Thanks Nina and Rendi.

Tom G.

From: Marano, Nina (CDC/OID/NCPDCID)
Sent: Tuesday, September 14, 2010 7:15 PM
To: Gomez, Thomas M. (CDC/OID/NCZVED)
Cc: Murphree, Rendi (CDC tn.gov (CDC tn.gov))
Subject: RE: USDA-APHIS-AC request for poster/presentation on TN TB in elephants investigation

Hi Tom

Here is my discussant talk. I am ccing Rendi Murphree who is the lead author for the EIS poster and the Grand Rounds presentation to see if she can send copy of poster, etc.

Thanks Nina

From: Gomez, Thomas M. (CDC/OID/NCZVED)
Sent: Tuesday, September 14, 2010 10:03 AM
To: Marano, Nina (CDC/OID/NCPDCID)
Cc: Gomez, Thomas M. (CDC/OID/NCZVED)
Subject: USDA-APHIS-AC request for poster/presentation on TN TB in elephants investigation

Hi Nina,

I just went by your office to discuss the following request –

Dr. Nora Wineland is the Director of the Center for Animal Welfare (USDA-APHIS-Animal Care). She learned about a poster at the EIS conference titled "outbreak of Mycobacterium tuberculosis infection among employees of an elephant refuge" and the 8/3 Epi Grand Rounds on the TB exposure of staff at an elephant sanctuary in TN. Nora is asking if she can get a copy of the poster and the Epi Grand Rounds presentation.

I assume it was the same lead author for the poster and Epi Grand Rounds - correct? If so, do you have the person's name so I can send them this request? Also, can you share your discussant presentation (PPT or PDF)?

Thanks,

Tom G.

[attachment "Final Poster for TB meeting 56 x 28.jpg" deleted by Nora E Wineland/CO/APHIS/USDA]
[attachment "Marano elephant1 NC.PPTX" deleted by Barbara A Kohn/MD/APHIS/USDA]



Barbara A
Kohn/MD/APHIS/USDA
09/16/2010 10:38 AM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Stat Pak tests 

Denise -

I will try to call this afternoon (my time) as I am still getting through e-mails that I couldn't handle completely with just the BB. I don't know if you have addressed this yet, but I drafted this and a hopefully simple step=process for certified accredited attending veterinarians. Does this make sense? I think we need some of the caveats on the document for clarity and thought processes....

let me know what you think.

Barb

Protocol for allowing access to Stat Pak by accredited vets

****The access to the Stat-Pak was developed to allow certified and accredited veterinarians to purchase and use the elephant TB test for unofficial testing of animals, including some other species of exotic hoofstock at exhibit facilities. Acquisition of all tests will be recorded to prevent fraudulent use on domestic species****

Discussions and negotiations with Veterinary Services (including NVSL and Biologics staffs) to address concerns about the accessibility of this test and possible misuse and interference with domestic and cervid TB programs, resulted in the following process to provide access and control (to provide oversight) of the restricted use licensed Chembio ElephantTB Stat-Pak rapid test kit. Requiring accreditation through VS provides tool to address improper use of the test kits.

Step 1: Attending veterinarian at facility with elephants requests access to the Chembio test kit

Interested facility or veterinarian contacts Animal Care to discuss training course

Step 2: Certifying training session must be arranged

Veterinarians (of facilities) are required to organize training that is economical (multiple trainees – recommend regional training

Veterinarians must provide facilities with sufficient number of elephants to testing

Facilities are responsible for cost of the test kits used for training

Training is one day, classroom and practical

Facilities may be required to pay for Chembio representative

Step 3: Certification training by APHIS/Chembio

Step 4: Licensing information, address, accreditation information provided by veterinarian

This is used to find listing on the database of accredited veterinarians maintained by VS

Step 5: Accreditation status is confirmed by AC and informs Chembio of status of veterinarian

Animal Care Staff veterinarian has official access to the accreditation database to confirm accreditation. Information on certified accredited veterinarians is provided to Chembio for their approved list of who is certified to order and use the test kits..

Step 6: Accredited, certified veterinarian is able to order and use test kit directly from Chembio for any unofficial tests

*****Animal Care certified (trained) VMO must oversee all official Chembio tests for elephant TB monitoring according to USAHA approved guidelines.



Barbara A
Kohn/MD/APHIS/USDA
03/26/2010 12:26 PM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: stat-pak auth. from states

I am getting my own share - Just off the phone with CA State Vet.....

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
03/26/2010 12:19 PM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject stat-pak auth. from states

Hi Barb,

More questions about state auth. for stat-paks. probably should have given them your contact information as well.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

----- Forwarded by Denise M Sofranko/NM/APHIS/USDA on 03/26/2010 10:18 AM -----



Denise M
Sofranko/NM/APHIS/USDA
03/26/2010 08:06 AM

To Robert C Brady/MA/APHIS/USDA
cc
Subject Re: Are you the person to contact about elephant TB testing?

Hi Bob,

Yes, I can answer questions about the new test and the TB Guidelines for Elephants.

Either of you can reach me at (b)(6) home/office (private number) or cell (b)(6)

Thanks!

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care
Robert C Brady/MA/APHIS/USDA

Robert C
Brady/MA/APHIS/USDA
03/26/2010 08:03 AM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc

Subject Are you the person to contact about elephant TB testing?

Dr. Sofranko,

Our Connecticut state vet, (b)(6) had questions for me about a new diagnostic test for TB in elephants that needs her approval to be used in her state. I wanted to make sure you are still the right person for questions about TB diagnostics in elephants before I gave (b)(6) our contact info.

Thanks,

Bob

Robert C. Brady, DVM, DACVPM
Area Epidemiologist
USDA APHIS Veterinary Services
PO Box 787
160 Worcester-Providence Road
Sutton, MA 01590
telephone 508-363-2296
robert.c.brady@aphis.usda.gov
fax 508-363-2272



Barbara A
Kohn/MD/APHIS/USDA
03/24/2010 03:43 PM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc

Subject Draft for WI epi, etc?

Denise -

Sorry it took longer than I was planning....does everyone want something right now???

Here is a draft summary that I think we can use, but it might need some refining...feel free. I attached 3 letters/memos.

Thanks.

Barb



Summary letter draft for state officials march 2010.doc

Elephant TB testing protocols

In October 2008, U.S. Animal Health Association (USAHA) approved revised guidelines for the testing and treatment of tuberculosis (TB) in elephants. USAHA recommended that APHIS adopt and implement the new guidelines, and APHIS agreed to do so. APHIS had been using prior editions of the guidelines to monitor TB in Animal Welfare Act (AWA) regulated elephants since 1998.

The 2008 guidelines continue to be based on the trunk wash as the definitive test, but a new test has been added to augment this protocol. The ElephantTB Stat-Pak (from Chembio) is to be used in conjunction with the trunk wash. This new test is licensed by the Center for Veterinary Biologics (APHIS) with use limited to approved laboratories. APHIS, Animal Care, Veterinary Services, Center for Veterinary Biologics, and the National Vet Services Laboratory (NVSL) worked in conjunction to develop a protocol that allowed for use of this test on site by certified Federal veterinarians (official required tests). NVSL will still run the test when requested, as well. Although certain accredited non-federal veterinarians may be certified for using the kit for unofficial tests, APHIS will be apprised of kit use.

Official testing of elephants can be done only under the direct supervision of the certified Animal Care veterinarian, with positive animal identification. If the testing is not done on site by the federal veterinarian, the samples collected will be handled, packed and shipped to NVSL following chain of custody procedures, including positive animal identification. The testing protocol has been developed to prevent fraudulent results.

Chembio still requires approval by the State veterinarian to ship the test kits into the State. Test kits used for official testing will be sent to the certified Animal Care veterinarian, who will hand-carry them to the facilities being tested. If the State veterinarian does not approve the entry of the test kits into their state, certified Animal Care veterinarians will supervise the identification and blood draws for the elephants, and oversee the packaging and shipment of the samples to NVSL.

State Veterinarians and Area Veterinarians in Charge have been kept apprised of this new testing program, as have AWA licensees with elephants (see attached letters). We also have the guidelines and a FAQ sheet available on our website (www.aphis.usda.gov/animal_welfare).

APHIS will work with State veterinarians to coordinate reporting of results and cooperate in addressing concerns about any unofficial testing at zoological facilities.

Dear Licensees with Elephants:

The Animal and Plant Health Inspection Service (APHIS) has required the testing of elephants for tuberculosis (TB) since 1998, as specified in the "Guidelines for the Control of Tuberculosis in Elephants." This document, written by the National Tuberculosis Working Group for Zoo and Wildlife Species, has been updated several times since 1998. In October 2008, the United States Animal Health Association approved the most current updates to this document and requested that APHIS adopt this updated version.

APHIS has adopted this most recent approved version of the Guidelines, and they can be found on our website (www.aphis.usda.gov/animal_welfare/) under Publications and Reports. A printed copy of the Guidelines was sent to all elephant licenses earlier this year.

The Guidelines incorporate a new blood test, the Elephant TB Stat-Pak®, in addition to the current trunk wash protocol. APHIS will implement this new requirement beginning in or around March 2010; facilities must accomplish this new testing protocol prior to March 2011. Testing the first year must be done under the direct supervision (blood draw) of a Federal AC veterinarian, with the Federal veterinarian either performing the test him/herself, or supervising the handling, packing, and shipping of the samples to the National Veterinary Services Laboratory. Guidelines for training of accredited veterinarians will be posted soon on our web site.

All AC veterinarians responsible for overseeing the new test will be trained prior to the March 2010 implementation date. State veterinarians have been issued an invitation to observe this new protocol, and may be in attendance when testing occurs at your facility.

During the official testing, APHIS will review and observe your trunk wash protocols to detect any collecting, handling, and shipping errors that could result in invalid tests. After the first year of testing, AC will evaluate the program and consider changes in the oversight process.

We appreciate your support of these new procedures and will be happy to answer any questions you might have regarding the protocol outlined above. Please contact my office if there are any further questions about this new process.

Sincerely,

Regional Director
Animal Care

Dear State Veterinarians and Area Veterinarians in Charge:

Under the Animal Welfare Act (AWA), APHIS has been testing captive elephants for tuberculosis (TB) since 1998. To date, the test used as the standard is a trunk wash with culture and sensitivity. The monitoring and testing protocols are based on guidelines developed by the National TB Working Group for Zoo and Wildlife Species in 1998, with updates in 2000 and 2003.

The 2008 guidance update was submitted to the United States Animal Health Association (USAHA) for consideration, and approved by the TB Committee in October 2008. The USAHA recommended that APHIS, Animal Care (AC) accept the 2008 updates and implement the monitoring and treatment programs outlined in the document. AC has agreed to implement the updated guidelines. A new test, the Chembio Elephant TB Stat-Pak®, will be performed pen side in addition to the required trunk washes. AC has worked with Veterinary Services (VS) representatives to make sure that our implementation is compatible with other TB programs within APHIS.

After a period needed to address concerns from some stakeholders, the certification and training of AC veterinarians is scheduled to begin in January/February 2010, with official testing of elephants scheduled to begin in or around March 2010. Only trained and certified AC veterinarians will monitor the blood collection and run and record the test results for the first year. After the first year, AC will evaluate the program and consider modifying direct AC oversight of the tests. States will continue to have the authority to determine testing requirements that may exceed the Federal mandates. At the present time, only approved laboratories can buy or run the tests; the VS National Veterinary Services Laboratories (NVSL) is the sole approved laboratory. The AC certification and oversight program will allow for the use of the test on site.

We wish to extend an invitation to the State Veterinarians and Area Veterinarians in Charge to observe the testing procedures. Please contact your nearest AC Regional Office if you wish to observe.

The TB guidance document, AC Policy "Control of Tuberculosis in Regulated Elephants," and any additional information about this program will be available on our website. We will be contacting our elephant holders shortly to provide them with this same information. If you have any questions, please call Dr. Denise Sofranko (240-461-9142) or Dr. Barbara Kohn (301-734-8271).

Sincerely,

Chester A. Gipson
Deputy Administrator
Animal Care

To: All Animal Care (AC) Employees

From: Chester Gipson, Deputy Administrator
Animal Care

Re: New Elephant Tuberculosis (TB) Testing Guidelines

AC is implementing the new TB guidelines for elephants that were approved by USAHA in October 2008. This document can be found on our website at (http://www.aphis.usda.gov/animal_welfare/downloads/elephant/elephant_tb.pdf). AC has developed a protocol for the new testing requirements, including the direct oversight of the blood test by trained, certified Veterinary Medical Officers (VMOs) and review of trunk wash procedures. A certified VMO (CV) will oversee the on-site testing of each facility, but the home inspector will be involved in the testing process, including facilitating the scheduling of the testing. AC must make a positive identification of each elephant, observe the drawing of blood from each elephant (or noting if the elephant cannot be bled by facility personnel), perform the test, and record the test results. The home inspectors and CVs will work together to arrange the testing. The CV will be responsible for the testing at the assigned elephant facility. Other inspectors may be called upon to help at the larger facilities. SACS will help to coordinate the scheduling of testing and extra inspectors to help out. AC will evaluate the need for continued direct oversight after the first year of testing.

Training and certification of selected AC VMOs (CVs) will take place in January/February 2010, and we will start the testing in or around March 2010. A CV will be assigned to each facility holding elephants. The home inspectors for these facilities should work with the CV and the licensees to schedule the testing of the elephants. We are allowing a year to complete this testing, timing it to coincide with scheduled trunk washes.

AC has contacted the State veterinarians and the VS Area Veterinarians in Charge to ensure that all parties are aware of our activities. The guidelines have been posted on the website, and a Frequently Asked Questions (FAQ) document will be posted shortly.

For your information, we have attached the documents: the letter sent to licensees, and the letter to the State Veterinarians and AVICs. If you are the home inspector for any elephant facility, you will be provided with the name of your CV soon. If you have any questions, please contact your SACS, Dr. Denise Sofranko (Field Specialist for Elephants) or Dr. Barbara Kohn (Staff Veterinarian for Exhibition Animals).



Barbara A
Kohn/MD/APHIS/USDA
03/19/2010 02:34 PM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: Fw: Stat Pak and other related questions

Denise -

The letters to State Vets went out last Friday. FL letter went to Dr. Holt. Really think we need to clarify the issue of testing with all involved - everyone seems to be interpreting the protocol to their own advantage. The FAQ is finally on the web - both on the home page for AC and on the publications page under elephants.....That info should help, too. I am out of here in 20 minutes, but will be in on Monday if we need to talk....

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
03/19/2010 01:29 PM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject Fw: Stat Pak and other related questions

Has the letter to state vets gone out yet? You may need to talk to Dr. Holt about this. We have been testing in FL. Don't want to get cross ways with anyone.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

----- Forwarded by Denise M Sofranko/NM/APHIS/USDA on 03/19/2010 11:28 AM -----



"Holt, Thomas"
<holtt@doacs.state.fl.us>
03/19/2010 11:26 AM

To "Crews, John" <crewsj@doacs.state.fl.us>,
<Denise.M.Sofranko@aphis.usda.gov>
cc <Gregory.S.Gaj@aphis.usda.gov>, "Jeter, Bill"
<jeterw@doacs.state.fl.us>, "Hunter, Pamela"
<hunterp@doacs.state.fl.us>, "Humphreys, Leigh"
<humphrl@doacs.state.fl.us>
Subject Re: Stat Pak and other related questions

Thanks, Dr. Sofranko. We must approve a company to send biologics to Florida. TB positives from any animal testing must be reported to us. Dr. Hunter and Dr. Jeter, let's look at a response on approving next week.

From: Crews, John
To: Denise.M.Sofranko@aphis.usda.gov <Denise.M.Sofranko@aphis.usda.gov>
Cc: Gregory.S.Gaj@aphis.usda.gov <Gregory.S.Gaj@aphis.usda.gov>; Holt, Thomas; Jeter, Bill
Sent: Fri Mar 19 12:00:55 2010
Subject: RE: Stat Pak and other related questions

Actually, I didn't specifically tell him about the quarantine but I think he got the picture.
Thanks for your response.

john

John E. Crews, DVM, MS
District (4) Veterinarian

Florida Department of Agriculture and Consumer Services
Division of Animal Industry / Bureau of Animal Disease Control
500 Third Street N.W. - Room 203B (Nora Mayo Hall)
Winter Haven, FL 33881
Office Phone: 863-297-3977 FAX: 863-297-3962

From: Denise.M.Sofranko@aphis.usda.gov [mailto:Denise.M.Sofranko@aphis.usda.gov]
Sent: Thursday, March 18, 2010 4:42 PM
To: Crews, John
Cc: Gregory.S.Gaj@aphis.usda.gov; Holt, Thomas; Jeter, Bill
Subject: Re: Stat Pak and other related questions

Hi John,

You're right. There is a lot of stuff flying around regarding all this testing. Keeping me busy, that's for sure.
;-)

I talked to (b)(6) yesterday to help sort some things out. He is aware that official testing has to be done under our supervision. Veterinarians that are certified to buy and use the test can test their own animals unofficially but for the official test, we need to either do it there and observe the blood draw, etc. or they run the test with us there and under the same oversight.

I had some of the same questions that I think you all are having and I think (b)(6) understands the issues here. He was not aware of the quarantine and I could only confirm it after he said he had heard that from you. I suspect he won't be testing those other animals and he knows that before they move that bull into their facility, they will need an official test. Dr. Gaj is aware of the situation as well.

Greg is the point person for the facilities in FI and will be sorting out the situation at Disney. While we might need to ask for your help in some of the testing, you will hear that from Greg or me as a request for help. Greg or one of the other AC VMOs who have been trained will also be giving information to Disney about ordering kits, etc.

The licensee is responsible for contacting (we'll give them this information) Chembio and ordering the test kits. The kits are then sent to the designated testing VMO and kept in their possession. The only exception to this is if there is a facility veterinarian who is certified. They can order the kits and have them at the facility but the tests must still be under supervision.

As for the diagnostic testing, we expect that the veterinarians will keep records on those and they will be available for our review. If you have the authority to review veterinary records (I assume so) you should be able to review those as well. We currently don't have any reporting requirements.

new challenge to be involved with this so my questions are information related and definitely not negative. I just want to do it right and I understand that I may just be called in to assist USDA AC staff at a particular premise. I am not sure who pays for the annual monitoring, so help me fill in the blanks. You may want to delegate some of the details to Greg Gaj, but wanted you to be in the questions loop.

Dr. Holt wanted to know if non-regulatory DVMs were going to be doing even the diagnostic testing... would the State Veterinarian's office be notified of the results of all testing or dependent on them reporting only the positive results.

That is enough questions to start the discussion. Thank you for help us sort through this and I am particularly grateful you allowed me to attend the training. Just hope that these questions don't change your mind about our involvement...just kidding!

John

John E. Crews, DVM, MS
District (4) Veterinarian

Florida Department of Agriculture and Consumer Services
Division of Animal Industry / Bureau of Animal Disease Control
500 Third Street N.W. - Room 203B (Nora Mayo Hall)
Winter Haven, FL 33881
Office Phone: 863-297-3977 FAX: 863-297-3962



Barbara A
Kohn/MD/APHIS/USDA
03/11/2010 06:59 AM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc
bcc
Subject Re: shipping costs for Stat-Pak testing

Yes. Since this is an inspection/enforcement program, cost are best taken from RO budgets (even though it all comes from the same pot).

Barb
Denise M Sofranko

----- Original Message -----

From: Denise M Sofranko
Sent: 03/10/2010 03:25 PM MST
To: Barbara Kohn
Subject: Fw: shipping costs for Stat-Pak testing

What do you think? Should we just divide by region?

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

----- Forwarded by Denise M Sofranko/NM/APHIS/USDA on 03/10/2010 03:25 PM -----



Robert M
Gibbens/CO/APHIS/USDA
03/10/2010 01:18 PM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc Barbara A Kohn/MD/APHIS/USDA@USDA, Betty J
Goldentyer/NC/APHIS/USDA@USDA
Subject Re: shipping costs for Stat-Pak testing

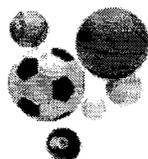
It's fine with me if each region pays for their own. Although if HQ wants to pay, that's fine too.
Denise M Sofranko

----- Original Message -----

From: Denise M Sofranko
Sent: 03/10/2010 01:13 PM MST
To: Robert Gibbens
Cc: Barbara Kohn; Betty Goldentyer
Subject: Re: shipping costs for Stat-Pak testing

The main question here is who should pick up the cost of shipping the kits to our 16 VMOs: East, West, HQ or a combination.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care
Robert M Gibbens/CO/APHIS/USDA



Robert M
Gibbens/CO/APHIS/USDA
03/10/2010 12:44 PM

To Denise M Sofranko/NM/APHIS/USDA@USDA, Betty J
Goldentyer/NC/APHIS/USDA@USDA, Barbara A
Kohn/MD/APHIS/USDA@USDA
cc

Barbara A
Kohn/MD/APHIS/USDA
03/11/2010 12:09 PM

To Denise M Sofranko/NM/APHIS/USDA (b)(6) chembio.com
cc
bcc

Subject Letter to State Vets regarding tb test kits.

We have the OK to send out the letters to the State Vets. I am working at home today and cannot print, so I will print the letters tomorrow when I am in the office and get them mailed out. Do I need to send to AZ? I think (b)(6) you already have the 2 facilities there cleared for shipment.

Thanks.

Barb

----- Forwarded by Barbara A Kohn/MD/APHIS/USDA on 03/11/2010 12:03 PM -----

Kay A
Carter-Corker/MD/APHIS/US
DA
03/11/2010 11:55 AM

To Barbara A Kohn/MD/APHIS/USDA@USDA
cc

Subject Letter to State Vets regarding tb test kits.

Andy answered my concerns. The letter as written is good to go. Thanks for being patient as I get up to speed on all that has happened before I arrived.

Sincerely

Kay A. Carter-Corker, D.V.M.
Assistant Deputy Administrator
Animal Care
4700 River Road, Suite 6D-03E
Riverdale, MD 20737
(301) 734-6328 (office)
(301) 734-4978 (Fax)



Subject Re: shipping costs for Stat-Pak testing

Denise - for the WR, check with Paula. I don't know enough to give an intelligent reply.
Denise M Sofranko

----- Original Message -----

From: Denise M Sofranko

Sent: 03/10/2010 10:29 AM MST

To: Robert Gibbens; Betty Goldentyer; Barbara Kohn

Subject: shipping costs for Stat-Pak testing

Hi all,

NVSL has been very helpful throughout all of the planning and lead up to our training and testing with Stat-Pak. In particular Tom Bunn and Jeff Nelson.

They have agreed to supply each of our testing VMOs with shipping supplies for sending serum samples to Chembio when they get Stat-Pak reactors and need to run them on MAPIA.

Most zoos and bigger facilities are already set up with appropriate supplies for that but we're likely to run into some that don't. We just had one last week. It's quite a scramble for the VMOs to get samples shipped when they don't have the supplies at hand. We want to have the kits on hand so if they are not readily available during the testing, the VMOs will have them. The licensee will still have to pay for shipping costs and the facilities that have all the supplies will still use their own.

Jeff is going to put together a couple of kits for each VMO that will include the shipping box with the styrofoam insert, whirl paks, and plastic cryo vials for serum. They will do this at no cost to AC.

I would to use our fedex acct. for shipping the boxes to the VMOs. Since we have separate accts for both regions and for HQ, I need to know which to use. It would be helpful if we could use the same acct. for all but if we need to divide by region, we could.

thanks!

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Barbara A
Kohn/MD/APHIS/USDA
03/09/2010 03:11 PM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: TB reporting table

Its OK - just cleaned up the heading for the last 2 columns, putting the words all on one line and making all the borders consistent. Nothing that will affect the data collection!

You are just too fast!

Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
03/09/2010 02:52 PM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject Re: TB reporting table

Not sure what you changed but I sent it out before I read this. Trying to keep my plate cleaned. ;-)

Let me know if it was a significant change. If not, I'll let them keep what they have.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care
Barbara A Kohn/MD/APHIS/USDA



Barbara A
Kohn/MD/APHIS/USDA
03/09/2010 12:36 PM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc
Subject Re: TB reporting table

Thanks -

I don't know if I saved it this way originally, but thought I would try to say so it could be filled..... Just 2 more tweaks in formatting. Then I say send it on to the trained vets.

Thanks.

Barb



Barbara A
Kohn/MD/APHIS/USDA
03/09/2010 02:38 PM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject RE: Stat-Pak State OK's 

So I was going through the spreadsheet of elephants and adding the state for my ease of use....just have to tease - you left out NJ on the list of states! Don't tell Karla!

Will add the state vet info to my data and all will be well!

Barb



Barbara A
Kohn/MD/APHIS/USDA
03/09/2010 02:36 PM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc
bcc
Subject Re: TB reporting table 

Thanks -

I don't know if I saved it this way originally, but thought I would try to say so it could be filled..... Just 2 more tweaks in formatting. Then I say send it on to the trained vets.

Thanks.

Barb

[attachment "Elephant TB StatPak reporting Table2010.doc" deleted by Barbara A Kohn/MD/APHIS/USDA]



Barbara A
Kohn/MD/APHIS/USDA
03/04/2010 03:46 PM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc
bcc
Subject Re: stat pak faq 

Denise -

I had meetings most of the day and now cannot get onto my computer remotely (hence the BB). I will look at it tomorrow and get back to you. Trish will be out tomorrow so can't put it on the web yet anyway.

Barb

Denise M Sofranko

----- Original Message -----

From: Denise M Sofranko
Sent: 03/04/2010 09:22 AM MST
To: Barbara Kohn
Subject: stat pak faq

I've added some more to this. Could you have a look and edit accordingly? I'd like to be able to put this on the web site and send it to all of our field staff (or at least the testing VMOs) and to send to licensees with questions. We might even just pull parts out to answer specific questions that come in.

[attachment "statpaktestingfaq.doc" deleted by Barbara A Kohn/MD/APHIS/USDA]

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Barbara A
Kohn/MD/APHIS/USDA
03/01/2010 11:47 AM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: Draft of cert letter to Konstantin for nongov vets 

Thanks, Denise...Just got the e-mail chain regarding FWS and Queenie....Maybe some movement on the issue tomorrow? Not holding my breath.

Have a safe drive to Ft. Collins....

Barb



Barbara A
Kohn/MD/APHIS/USDA
01/25/2010 09:04 AM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: reporting form

As I recall, it is an issue of convenience for Chembio so that they don't have to deal with checking each time that the person is on the list and the tests are being sent to the official address. It may have been to add an added control so we know which one it is. In addition, until the vets are certified (and I am not convinced all will qualify with the licensed and accredited requirements), they cannot officially order the tests. Because of the licensing requirement for Chembio, I think this was done to make sure they stayed in compliance by officially selling the tests to NVSL. Does that make sense?

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
01/25/2010 09:00 AM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject Re: reporting form

Thanks. I'm still holding my breath. ;-)

One other question: I'm trying to remember all the reasons we are going through NVSL for the payment part of this. Is there any reason why licensees couldn't just pay ChemBio directly?

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care
Barbara A Kohn/MD/APHIS/USDA



Barbara A
Kohn/MD/APHIS/USDA
01/25/2010 06:57 AM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc
Subject Re: reporting form

Here you go....can't believe we are actually doing this, finally! 2 formats - word doc and spreadsheet....take your pick.

Barb

Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
01/24/2010 05:35 PM

To Barbara A Kohn/MD/APHIS/USDA
cc



Subject reporting form

I may be able to find it by morning but could you send me the reporting form you made up for the Stat-Pak tests.

Just getting last minute details taken care of here.

thanks!

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Barbara A
Kohn/MD/APHIS/USDA
01/25/2010 08:57 AM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc
bcc

Subject Re: reporting form 

Here you go....can't believe we are actually doing this, finally! 2 formats - word doc and spreadsheet....take your pick.

Barb

[attachment "Elephant TB StatPak reporting table draft Jan 2009.xls" deleted by Barbara A Kohn/MD/APHIS/USDA] [attachment "Elephant TB StatPak reporting Table draft 2009.doc" deleted by Barbara A Kohn/MD/APHIS/USDA]
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
01/24/2010 05:35 PM

To Barbara A Kohn/MD/APHIS/USDA
cc

Subject reporting form

I may be able to find it by morning but could you send me the reporting form you made up for the Stat-Pak tests.

Just getting last minute details taken care of here.

thanks!

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Barbara A
Kohn/MD/APHIS/USDA
01/15/2010 10:13 AM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: Draft letter template for Chembio certified list 

For legality sake, we do probably need the license number for the state of residence. Good catch. We are suppose to have access to the list of accredited vets. I think the last time I tried, I had trouble accessing (it is a VS database, so problems are to be expected). We can get Clem and/or Todd to make sure we have access.... Do we want to include a check mark in the table we send to Chembio, or function on the basis that we are only sending lists of accredited and certified parties...we could just add that verbiage to paragraph one. I would like to keep the table in the actual letter (embedded) to avoid any concerns that some one has a table that may not have originated from us....

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
01/15/2010 10:07 AM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject Re: Draft letter template for Chembio certified list 

Looks good.

We're going to have to verify license and registration. Should we just have them send in proof of that or should I look at it on site? I guess the vet accred. would have the list of accred. vets.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care
Barbara A Kohn/MD/APHIS/USDA



Barbara A
Kohn/MD/APHIS/USDA
01/15/2010 07:35 AM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc
Subject Draft letter template for Chembio certified list

Denise -

What do you think? Kept it short...we can just send updates they can add to.... Do we need more info for them?

Barb



Approved lab letter to Chem Bio template.doc



Barbara A
Kohn/MD/APHIS/USDA
01/15/2010 09:35 AM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Draft letter template for Chembio certified list

Denise -

What do you think? Kept it short...we can just send updates they can add to.... Do we need more info for them?

Barb



Approved lab letter to Chem Bio template.doc



United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

4700 River Road
Unit 84
Riverdale, MD
20737

(b)(6)

Chembio Diagnostic Systems, Inc.
3661 Horseblock Road
Medford, NY 11763

Deal (b)(6)

Please find included a list of approved parties who have been certified by USDA, APHIS, Animal Care, to be eligible to order and receive the Elephant Stat-Pak® test kits manufactured and distributed by your company. The certification process developed by this office meets the licensing requirements of the test kit. These names should be added to you records as approved customers.

Name	Street Address	City	State	Phone

Please feel free to contact Drs. Sofranko (240-461-9142) and Kohn (301-734-8271) if there are any questions or concerns.

Sincerely,

Chester A. Gipson
Deputy Administrator

cc: Mr. Jeff Harestad, CVB-IC, PO Box 844, Ames, IA 50010





Barbara A
Kohn/MD/APHIS/USDA
01/12/2010 12:01 PM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: Fw: Stat-Pak test

OK -

If you get me the name at Chem Bio, I can work on the letter tomorrow....

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
01/12/2010 11:56 AM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject Fw: Stat-Pak test

I think we should just work up a letter/memo from Chester that we can send with the names and we should be good. I think a letter sent to Chem Bio as soon as possible (so they can get the kits in the mail) authorizing me to receive them on behalf of AC should do it.

(b)(6) is their regulatory person but I'll check on the name of the person at Chem Bio that should receive the letter. We should be able to e-mail with a hard copy follow up.

Something like:

Dr. Denise Sofranko as a representative of APHIS/Animal Care is authorized to received Stat-Pak test kits from Chem Bio.

Could you do that this week yet? I'll have them overnight the kits to me in ABQ and just hand carry them to Tampa and have them here for ABQ.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

---- Forwarded by Denise M Sofranko/NM/APHIS/USDA on 01/12/2010 09:52 AM ----



Larry R
Ludemann/IA/APHIS/USDA
01/12/2010 09:43 AM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc Barbara A Kohn/MD/APHIS/USDA@USDA, Thomas O
Bunn/IA/APHIS/USDA@USDA, Jeff
Harestad/IA/APHIS/USDA@USDA
Subject Re: Stat-Pak test

Denise:

Animal Care should maintain a list of approved individuals and laboratories for this test. A letter from AC

to ChemBio indicating the approved laboratories will be sufficient for ChemBio to meet the license restriction. Please cc: Mr. Jeff Harestad, CVB-IC, P.O. Box 844, Ames, IA 50010 with the list of approved laboratories. ChemBio will also have to obtain state approval separately.

In my opinion, you will not need to send anything to ChemBio allowing you to receive the test kits. To me, AC represents APHIS and you represent the elephant program as far as the license restriction is concerned.

Larry Ludemann
Senior Staff Veterinarian
USDA, Center for Veterinary Biologics-Policy, Evaluation, Licensing
1920 Dayton Avenue
P.O. Box 844
Ames, IA 50010
(515) 337-6100
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
01/12/2010 09:42 AM

To Larry R Ludemann/IA/APHIS/USDA@USDA, Thomas O
Bunn/IA/APHIS/USDA@USDA
cc Barbara A Kohn/MD/APHIS/USDA
Subject Stat-Pak test

Hi Larry,

We're getting ready to begin training VMOs to run the Stat-Pak test in the field and need to know how best to designate certification to use the test in the field.

We will be training our VMOs along with a handful of facility veterinarians in the next few months.

Would a simple letter to ChemBio with a list of people be sufficient or do we need something more? If so, who should such a letter come from?

Also for the first training period in Tampa, we need some kits sent from Chem Bio so we can use them for the training. Chem Bio would rather they be shipped to me and I can hand carry them to Tampa. Do we need to send something to Chem Bio to give them the ok to ship kits to me?

If you would like to discuss this by phone, you can reach me at 505-332-2778.

Thanks!

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Barbara A.
Kohn/MD/APHIS/USDA
01/08/2010 09:29 AM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc
bcc
Subject Re: certification letter/form? 

Will look into it. I think a simple letter format will do, but I think we should definitely use a cert number for those trained for trace back purposes. I am at home for another few minutes (light snow delayed school 2 hrs) and then will be in the office. Should get the MRP-13 done early afternoon.

Barb
Denise M Sofranko

----- Original Message -----

From: Denise M Sofranko
Sent: 01/08/2010 06:52 AM MST
To: Barbara Kohn
Subject: certification letter/form?

Hey Barb,

We'll need to have some sort of form or letter showing who is certified to purchase and use the Stat-Pak in the field. I don't think we had that developed for the last go 'round.

What format do you think should be used?

Prior to the first testing session, we need to give ChemBio permission to send the kits to the field for the training. They don't want Konstantin to hand carry.

I think that can be done with a letter but not sure who it should come from.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Barbara A
Kohn/MD/APHIS/USDA
10/02/2009 11:51 AM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: Updated documents for TB Testing and training October 2009 

Will do if there is room (1-page letters). Will check with Andy and Chester.

Thanks.

Keep backing away!
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
10/02/2009 11:48 AM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject Re: Updated documents for TB Testing and training October 2009 

In the letter to AC and to licensees, do you want to put a short sentence to explain/remind them of the reason for the delay in the training and testing similar to what you put in the state vet letter?

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Barbara A
Kohn/MD/APHIS/USDA
10/02/2009 11:48 AM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: Updated documents for TB Testing and training October 2009 

Thanks! Will do it either later today or on Monday! And your are NOT suppose to be working today!

Have a great weekend....

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
10/02/2009 11:42 AM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject Re: Updated documents for TB Testing and training October 2009 

Hey Barb,

I'm going through all these docs but wanted to get a change to you before I forget. In the new guidelines, it still lists my old voice mail number. That needs to be deleted and replaced with the general number for the Fort Collins office. Also, delete my fax number. A lot of people already have my office and cell phone number and can reach me that way. Others can use e-mail or call the region. This needs to be changed on the version that is on the website as well.

thanks!

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Barbara A
Kohn/MD/APHIS/USDA
09/17/2009 12:18 PM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject AAZV meeting issues



Denise -

Mike says he has heard back from Chester. First, he doesn't remember Indianapolis being excluded. I still think we need to move on from them and can use the nonresponse as a reason. Second, Chester says Kevin does expect us to work with EMA, so Mike and I agree to set up the 4th training site at Baltimore, as Mike is on the EMA board. Someone had the impression that EMA and AZA were upset that we didn't work through their boards instead of the facilities. I don't get it or think it should be an issue....

How did things go this AM?

Barb



Barbara A
Kohn/MD/APHIS/USDA
09/15/2009 10:58 AM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: Background info for updates for AZA meeting 

Lovely.....thought we were pretty clear.....

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
09/15/2009 10:56 AM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject Re: Background info for updates for AZA meeting 

Hey Barb,
There is some indication from reports received from a session yesterday that AAZV is looking at responding to our response. Guess they don't consider the issue resolved. I'll see if I can get more info. today.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Barbara A
Kohn/MD/APHIS/USDA
09/10/2009 07:54 AM

To Denise M Sofranko/NM/APHIS/USDA
cc Laurie J Gage/CA/APHIS/USDA@USDA, Ray M Flynn/CO/APHIS/USDA@USDA
bcc
Subject Re: Background info for updates for AZA meeting

Denise -

I think the approach below will work well. Maybe a quick word about what the new guidelines mean - like what tests are required and that Stat-Pak is a screening test. If positive, need MAPIA. Test is considered real positive only if MAPIA positive. Then discuss our certification approach and possible timetable (starting testing next year). It is okay to allude to the fact that our program is based on obtaining nonfraudulent compliance from all regulated parties and that APHIS will be very pliable in scheduling yearly observed tests at the facilities' convenience. If there are real questions about the AAZV letter and our response, ask (b)(6) we can get copies to those who want it...AZA should have access to the letter as a member who met with (b)(6) is usually at the roundtable and he may volunteer the letter). One would hope that AZA is chagrined enough about being linked to RBBB that they won't focus on this....

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
09/09/2009 04:53 PM

To Barbara A Kohn/MD/APHIS/USDA
cc Laurie J Gage/CA/APHIS/USDA@USDA, Ray M Flynn/CO/APHIS/USDA@USDA
Subject Re: Background info for updates for AZA meeting

I sent you a ppt. earlier that outlines the new guidelines but after seeing the topics list, I think I'll change course. All the licensees received the new guidelines and I can answer questions on those if they have them but I think maybe just explaining the delay and telling them that we've addressed concerns and are getting back on track might be best. I don't think that will require a ppt.. Still open for suggestions if you think I should talk more about guidelines.

I'm sure during the conference I'll be having side conversations about this as well.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care
Barbara A Kohn/MD/APHIS/USDA



Barbara A
Kohn/MD/APHIS/USDA
09/09/2009 11:54 AM

To Ray M Flynn/CO/APHIS/USDA@USDA, Denise M Sofranko/NM/APHIS/USDA@USDA, Laurie J Gage/CA/APHIS/USDA@USDA
cc
Subject Background info for updates for AZA meeting

Ray, Denise, Laurie -

Here are the main issues (some are tried and true areas of inquiry) that I would update on if I was at the meeting.

Please let me know if there are other issues that you think will be raised (like Boo). We can try to put info together if you need it.

Just to note, we have more dockets in the process, but these are the main ones that this group follows.

Thanks.

Barb

(this is really '09, just mislabeled) It is a list of the current dockets if you need other info



Barbara A
Kohn/MD/APHIS/USDA
09/08/2009 04:46 PM

To Denise M Sofranko/NM/APHIS/USDA
cc Laurie J Gage/CA/APHIS/USDA@USDA, Ray M
Flynn/CO/APHIS/USDA@USDA
bcc
Subject Re: Fw: AZA Annual Conference session

It will be your choice...We usually do it a capella (no formal presentation) but if the info is more easily presented in slide format, go ahead. They always have the equipment to handle it...

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
09/08/2009 04:42 PM

To Ray M Flynn/CO/APHIS/USDA@USDA
cc Barbara A Kohn/MD/APHIS/USDA@USDA, Laurie J
Gage/CA/APHIS/USDA@USDA
Subject Re: Fw: AZA Annual Conference session

Do you think I should use a power point or just talk for a few minutes?

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care
Ray M Flynn/CO/APHIS/USDA



Ray M
Flynn/CO/APHIS/USDA
09/08/2009 02:41 PM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc Barbara A Kohn/MD/APHIS/USDA@USDA, Laurie J
Gage/CA/APHIS/USDA@USDA
Subject Re: Fw: AZA Annual Conference session

The TB test implementation and associated updates to the Guidelines are a significant regulatory undertaking in the eyes (or barns) of some of the attendees. In keeping with something closer to a panel-format session, it would be helpful to have you take a few minutes to cover the changes, the plan, and the rationales for same. That gets our cards on the table first, in an affirmative and informational way, and provides context for those listening who might otherwise obtain an abbreviated version (ahem!) from a questioner. --You might also mention Barb's participation in development of the plan, note that she's not present, and comment that it takes at least 3 of us to substitute for her presence.

Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
09/03/2009 03:53 PM

To Ray M Flynn/CO/APHIS/USDA@USDA
cc Barbara A Kohn/MD/APHIS/USDA@USDA, Gwynn M
Hallberg/OR/APHIS/USDA@USDA, Kevin M
Dennison/CO/APHIS/USDA@USDA, Laurie J
Gage/CA/APHIS/USDA@USDA
Subject Re: Fw: AZA Annual Conference session



I can be there for both sessions. I'm expecting questions about TB and the recent confiscation. I won't worry about having anything formal but will have my talking pts. ready.

thanks!

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care
Ray M Flynn/CO/APHIS/USDA



Ray M
Flynn/CO/APHIS/USDA
09/03/2009 03:48 PM

To Denise M Sofranko/NM/APHIS/USDA@USDA, Laurie J
Gage/CA/APHIS/USDA@USDA, Gwynn M
Hallberg/OR/APHIS/USDA@USDA, Kevin M
Dennison/CO/APHIS/USDA@USDA
cc Barbara A Kohn/MD/APHIS/USDA@USDA

Subject Fw: AZA Annual Conference session

Denise and Laurie--if you can come to at least part of the roundtable session on Tuesday as well as the more formal one on Thursday discussed previously, that would perhaps be helpful. If there are elephant TB testing questions for Denise, some may land at that time.

They have not had this session every year, and I remember attendance as somewhat sparse. Some of the traffic came from people just sitting down at one of the regulatory roundtables to eat lunch.

Gwynn and Kevin--your call. It is a venue for stakeholder feedback, and can be interesting depending on who shows up.

----- Forwarded by Ray M Flynn/CO/APHIS/USDA on 09/03/2009 03:38 PM -----



Barbara A
Kohn/MD/APHIS/USDA
09/03/2009 10:32 AM

To "Ray Flynn" <ray.m.flynn@aphis.usda.gov>
cc

Subject Fw: AZA Annual Conference session

FYI

From (b)(6)@AZA.org]
Sent: 09/03/2009 12:30 PM AST
To: "Jennifer Skidmore" <Jennifer.Skidmore@noaa.gov>; Barbara Kohn; "Mike Carpenter"
<michael_carpenter@fws.gov>
Subject: FW: AZA Annual Conference session

Just a reminder:

The Regulations session will be Thursday, September 17th from 8:30 - 10:00am. I have also reserved three roundtables for the exhibit hall on Tuesday, September 15th from noon until 1:30pm if AZA members would like to discuss individual issues with you all. Hope this works for all of you.

Barb--could you please pass this on to Ray and the others?

All the best,

(b)(6)



Barbara A
Kohn/MD/APHIS/USDA
07/10/2009 01:18 PM

To Denise M Sofranko/NM/APHIS/USDA, James M
Tuck/MD/APHIS/USDA

cc

bcc

Subject New draft of elephant TB letter from Kevin to AAZV

Denise and Mike -

I have incorporated Denise's comments and some additional information provided. New language is in blue! Not married to the last item in attachment 1, but is both APHIS and USAHA say it, maybe they will listen???

Denise - your recommended changes have been incorporated and are now in black

I tried to go through and used Elephant Stat-Pak for references to the test kit, as well as in our responses refer to the company as Chembio. Hopefully that makes for a consistent format

Barb



Response to AAZV et al Kevin meeting.doc



Barbara A
Kohn/MD/APHIS/USDA
07/09/2009 03:44 PM

To Denise M Sofranko/NM/APHIS/USDA, James M
Tuck/MD/APHIS/USDA
cc
bcc

Subject Draft 1, AAZV elephant response (TB guidelines)

Denise and Mike -

Thanks, Denise for all of the info and work you did to provide the materials for the response draft. Naturally, I have edited some and added other stuff. Sorry for the length, but I think we needed to get it all in writing so we can move on...Almost choked at the ending paragraph, but I think we have to say it...

Please let me know what you think.

Thanks,

Barb



Response to AAZV et al Kevin meeting.doc



Barbara A
Kohn/MD/APHIS/USDA
07/09/2009 01:35 PM

To Denise M Sofranko/NM/APHIS/USDA
cc James M Tuck/MD/APHIS/USDA@USDA
bcc
Subject Re: Follow up on Bullet 7

Thanks, Denise. I will try to get these incorporated into a letter this afternoon. If that is not possible, first thing in the AM. If you have any more information or revisions to what has been provided, please pass them along.....

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
07/09/2009 01:31 PM

To Barbara A Kohn/MD/APHIS/USDA, James M
Tuck/MD/APHIS/USDA@USDA
cc
Subject Follow up on Bullet 7

Bullet 7:

As we implement these new Guidelines, there will likely be scenarios that are not specifically addressed in the Guidelines. In those instances, we are prepared to consult with appropriate experts and with the facility veterinarians, to provide proper guidance on how these cases should be handled.

In this particular scenario, if the trunk wash is negative, there would be no travel restrictions and follow up testing frequency would depend on current or prior exposure to TB and other factors. This would all be discussed with facility veterinarians to ensure that the action most appropriate for the elephant is taken.

If the Elephant TB STAT-PAK is reactive but MAPIA negative the final result is NEGATIVE (for TB, not necessarily for other pathogenic mycobacteria). Such findings may constitute 3-5% of the captive elephant population, and that is why we need MAPIA (or DPP) to confirm each STAT-PAK reactive sample. As the 2006 paper discussed, there may be a very slim chance that STAT-PAK detects specific antibodies early during TB while MAPIA (or DPP) is temporarily negative, from several weeks to 2-3 months, before IgG seroconversion (based on a single case finding, so far). But since we cannot exclude this rare possibility, it is recommended to follow up on such elephants (STAT-PAK reactive but MAPIA/DPP negative) within several months by serology, in addition to taking an additional trunk wash for culture. Of course, any clinical symptoms or recent exposure to a known TB case would need to be taken into consideration, as this would enhance the likelihood of infection.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Barbara A
Kohn/MD/APHIS/USDA
07/08/2009 05:10 PM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: Elephants and TB - what else!

OK, here is the USAHA letter....In Adobe 8 (I have professional) by selecting all under the edit menu, it brings up a page to ask if you want to deconstruct the image. I say yes (2 steps I think), then save as a word document from Adobe. Hope that makes sense....

Anyway - here you go.

Barb



USAHA_elephant_To_letter_signed[1].doc
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
07/08/2009 05:04 PM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject Re: Elephants and TB - what else!

Thanks. That will be very helpful.

Can you do the same to the other one? I want to cut and paste the treatment statement and send it to Joel for comment. Don't want to send the whole letter and I won't give him any context. Just want his opinion.

And by the way, how did you convert that? I tried saving it as a word doc. but it didn't work.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Barbara A
Kohn/MD/APHIS/USDA
07/08/2009 04:59 PM

To Denise M Sofranko/NM/APHIS/USDA
cc James M Tuck/MD/APHIS/USDA@USDA
bcc
Subject Re: Elephants and TB - what else!

Denise -

try this file. You should be able to edit it. The letterhead is not quite the same, but it will make it easier for you to respond.

Barb



USDA_Tb_letter_signed.doc
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
07/08/2009 04:41 PM

To James M Tuck/MD/APHIS/USDA@USDA
cc Barbara A Kohn/MD/APHIS/USDA@USDA
Subject Re: Elephants and TB - what else!

Do either of you know if there is a way to convert pdf to text files so I can put answers right into the letters?
Easier for me to respond that way.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Barbara A
Kohn/MD/APHIS/USDA
07/08/2009 03:26 PM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Fw: Follow Up Letters to June 3 Meeting Re: Elephant Testing

Hope this opens for you!

----- Forwarded by Barbara A Kohn/MD/APHIS/USDA on 07/08/2009 03:27 PM -----



James M
Tuck/MD/APHIS/USDA
07/08/2009 02:55 PM

To Barbara A Kohn/MD/APHIS/USDA@USDA, Denise M Sofranko/NM/APHIS/USDA@USDA
cc
Subject Fw: Follow Up Letters to June 3 Meeting Re: Elephant Testing

Hi there,

Finally we got the response about the elephant testing. Your ideas for the response to their letters would be appreciated.

Thanks,

Mike T.

----- Forwarded by James M Tuck/MD/APHIS/USDA on 07/08/2009 02:51 PM -----

Chester A
Gipson/MD/APHIS/USDA
07/08/2009 08:59 AM

To Ray M Flynn/CO/APHIS/USDA@USDA, Robert M Gibbens/CO/APHIS/USDA@USDA, Betty J Goldentyer/NC/APHIS/USDA@USDA, Chester A Gipson/MD/APHIS/USDA@USDA, Yvette D Joyner/MD/APHIS/USDA@USDA, James M Tuck/MD/APHIS/USDA@USDA, Allan T Hogue/MD/APHIS/USDA@USDA, Thay Ly/MD/APHIS/USDA@USDA, Robert A Willems/NC/APHIS/USDA@USDA, Andrea M Morgan/MD/APHIS/USDA@USDA
cc
Subject Fw: Follow Up Letters to June 3 Meeting Re: Elephant Testing

I do not know if you received a copy. We will need to respond to the letter before we can implement the testing. Kevin ask Dr. Clifford to weigh in on the issue regarding the Accredited Vets and he has not responded officially.

Thanks,
C. Gipson
301 734 4980

----- Forwarded by Chester A Gipson/MD/APHIS/USDA on 07/08/2009 08:59 AM -----



(b)(6)
(b)(6)@feldinc.com>
07/07/2009 11:12 AM

To (b)(6)@feldinc.com>, "Chester Gipson (chester.a.gipson@aphis.usda.gov)" <chester.a.gipson@aphis.usda.gov>



cc

Subject RE: Follow Up Letters to June 3 Meeting Re: Elephant Testing

From (b)(6)

Sent: Tuesday, July 07, 2009 11:11 AM

To: Chester Gipson (chester.a.gipson@aphis.usda.gov)

Subject: Follow Up Letters to June 3 Meeting Re: Elephant Testing

Dr. Gipson:

I just received the attached from AAZV. These are the follow up letters to the meeting we (AAZV, AZA, Feld, Busch, EMA, etc) had with you and Mr. Shea regarding the new testing requirements for elephants (which we are aware have been withdrawn for the time being). I think these letters summarize the key issues and questions that we all had as to the testing requirements, the licensing restrictions and the revised Guidelines. AAZV sent these directly to Mr. Shea but I wanted to make sure you saw promptly too.

Thanks



(b)(6)

USAHA_elephant_Tb_letter_signed[1].pdf USDA_Tb_letter_signed.pdf



Barbara A
Kohn/MD/APHIS/USDA
06/08/2009 02:40 PM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: Fw: Stat-Pak license

Interesting, indeed.... Wonder if John C is feeling some heat? Wonder what it is all about..

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
06/08/2009 02:38 PM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject Fw: Stat-Pak license

Interesting reply.
I think Chester said he is tracking this information down so I should just back off and leave it to someone else. What do you think?

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

----- Forwarded by Denise M Sofranko/NM/APHIS/USDA on 06/08/2009 12:39 PM -----



Larry R
Ludemann/IA/APHIS/USDA
06/08/2009 12:32 PM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc
Subject Re: Stat-Pak license

Denise:

Without clear indications of the purpose of needing the actual letter or license, I have been asked to withhold giving you copies. The letter notifying the firm of the product license only indicates to note the restrictions on the license. You have been provided with the actual wording of the license restrictions.

Larry Ludemann
Senior Staff Veterinarian
USDA, Center for Veterinary Biologics-Policy, Evaluation, Licensing
510 South 17th Street, Suite 104
Ames, IA 50010
(515) 232-5785
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
06/01/2009 11:29 AM

To Larry R Ludemann/IA/APHIS/USDA@USDA
cc



Subject Stat-Pak license

Hi Larry,

Still working on the Stat-Pak issue here.

I've been asked to get the actual licensing notification that was given to Chem Bio for this test kit. I have the brief statement with restrictions of use that you sent in August of 2007 but is there a more complete notification or letter that was given to Chem Bio outlining restrictions of use and sale?

Thanks!

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Barbara A
Kohn/MD/APHIS/USDA
06/08/2009 10:22 AM

To Denise M Sofranko/NM/APHIS/USDA
cc James M Tuck/MD/APHIS/USDA@USDA, Chester A
Gipson/MD/APHIS/USDA@USDA
bcc

Subject Re: My first edit

I corrected a couple of typos that were evident once I switched the view to final (no mark-up). Here is the latest version. Chester, if you are OK with it, we can forward to Caffilene. Thanks.

Barb



TB stakeholder avic state vets response.doc
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
06/08/2009 09:20 AM

To Barbara A Kohn/MD/APHIS/USDA
cc James M Tuck/MD/APHIS/USDA@USDA
Subject Re: My first edit

I think short and concise is good.

I got hung up on the word "developed" in the sentence below. Maybe just not enough coffee but not sure it's needed

Unless there is some reason to stress "official copy," I would delete it and just say: "responded to the questions submitted by this group."

We feel it is important to address these questions and other issues raised by the implementation process developed. Therefore, implementation of the 2008 Guidelines testing requirements will be delayed until APHIS has responded to the official copy of the issues to be submitted by this group.

I think this delay is going to really confuse everyone so hopefully, we'll get the letter of concerns quickly and can deal with it.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care
Barbara A Kohn/MD/APHIS/USDA



Barbara A
Kohn/MD/APHIS/USDA
06/08/2009 07:12 AM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc James M Tuck/MD/APHIS/USDA@USDA
Subject My first edit

Denise -

Attached is my edits of the letter Chester sent to us on Saturday. Don't be scared of all of the red - wording is just rearranged or expanded. I think, if possible, this is to be sent to elephant holders, AVICs, and state vets....

Please let me know what you think.

Barb

[attachment "TB stakeholder avic state vets response.doc" deleted by Barbara A Kohn/MD/APHIS/USDA]



Barbara A
Kohn/MD/APHIS/USDA
06/08/2009 09:25 AM

To Denise M Sofranko/NM/APHIS/USDA
cc James M Tuck/MD/APHIS/USDA@USDA
bcc
Subject Re: My first edit

OK. I agree with your changes and think "developed" can be eliminated as well....here is copy #2:

Barb



TB stakeholder avic state vets response.doc
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
06/08/2009 09:20 AM

To Barbara A Kohn/MD/APHIS/USDA
cc James M Tuck/MD/APHIS/USDA@USDA
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Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care
Barbara A Kohn/MD/APHIS/USDA



Barbara A
Kohn/MD/APHIS/USDA
06/08/2009 07:12 AM

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cc James M Tuck/MD/APHIS/USDA@USDA
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Please let me know what you think.

Barb



TB stakeholder avic state vets response.doc

June 9, 2009

Animal Care recently distributed the Tuberculosis (TB) Guidelines (guidelines) approved by the United States Animal Health Association (USAHA) and plans for implementing the guidelines. Subsequently, members representing several organizations subject to the guidelines met with the Department to express concerns regarding the document and the implementation process. Primary questions raised include: Is this document distributed the guidelines as approved by the TB committee of USAHA; What was the justification for restricting the use of the Elephant TB Stat-Pak® test kit to use by USDA approved laboratories only; and Why it is necessary for Animal Care/APHIS to employ direct oversight of licensed, accredited veterinarians that could be approved as laboratories to use the test under the protocol developed by Animal Care. We feel it is important to address these questions and other issues raised by the implementation process. Therefore, implementation of the 2008 Guidelines testing requirements will be delayed until APHIS has responded to the issues to be submitted by this group.



Barbara A
Kohn/MD/APHIS/USDA
06/08/2009 09:12 AM

To Denise M Sofranko/NM/APHIS/USDA
cc James M Tuck/MD/APHIS/USDA@USDA
bcc
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Please let me know what you think.

Barb



TB stakeholder avic state vets response.doc



Barbara A
Kohn/MD/APHIS/USDA
06/04/2009 01:39 PM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject RE: Stat-Pak training

How nice!

----- Forwarded by Barbara A Kohn/MD/APHIS/USDA on 06/04/2009 01:41 PM -----



(b)(6)
(b)(6)
(b)(6)@indyzoo.com>
06/04/2009 01:38 PM

To "Denise.M.Sofranko@aphis.usda.gov"
<Denise.M.Sofranko@aphis.usda.gov>, (b)(6)
(b)(6)@INDYZOO.com>
cc "Barbara.A.Kohn@aphis.usda.gov"
<Barbara.A.Kohn@aphis.usda.gov>, (b)(6)
(b)(6)@INDYZOO.com>
Subject RE: Stat-Pak training

Denise: No problem. We'll await resolution of the concerns and discuss it again in the future. Talk to you soon, (b)(6)

From: Denise.M.Sofranko@aphis.usda.gov [mailto:Denise.M.Sofranko@aphis.usda.gov]
Sent: Thursday, June 04, 2009 12:40 PM
To: (b)(6)
Cc: Barbara.A.Kohn@aphis.usda.gov
Subject: Stat-Pak training

H (b)(6)

As you probably already know there are some concerns from some elephant industry groups about the Stat-Pak testing and the new elephant Tb Guidelines. Because of that, the Administrator has asked us to put a hold on the training sessions until we can answer those concerns.

We are hoping to be back on track with training once that is done but for the time being I wanted to let you both know that we won't be visiting your facility in June for the training session.

We appreciate your willingness to cooperate with us on this and appreciate the time and effort you have contributed to it.

Thank you.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Barbara A
Kohn/MD/APHIS/USDA
06/01/2009 09:59 AM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: TB + elephants 

Denise - Thanks for the table and the comments and edits on the documents. Chester wants to include a copy of the info on the box/licensing restrictions....we need to have in words that the test can only be ordered and run by approved labs.....I checked the Chembio website and their documents on line do not address. Tried CVB as well, and they do not allow access to the actual licenses...

Do you have or can you get ASAP the actual license or a copy of the box information? I will keep looking through my old files, but if you can access the info, great!

Mike is presenting the idea of getting on the VS State Vet conference call.....hopefully will hear today as well.

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
06/01/2009 09:26 AM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject TB + elephants

Here is the latest information I have on the positives. It's obvious that most are from circuses and in 2 particular.

[attachment "TB + elephants US.doc" deleted by Barbara A Kohn/MD/APHIS/USDA]

Might be helpful if anyone is wondering why certain licensees don't want elephant testing to see the light of day.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Barbara A
Kohn/MD/APHIS/USDA
05/29/2009 01:14 PM

To Denise M Sofranko/NM/APHIS/USDA
cc Ray M Flynn/CO/APHIS/USDA@USDA
bcc
Subject Re: help from FL 

I think that sounds like a great idea. It is the State veterinarians that we really need to be "partnering" with, not just the industry. I will run it by Mike and he can approach Andy and/or Chester (I really hate all these layers now!). Hope to have a draft of the info for Kevin this afternoon yet...

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
05/29/2009 01:03 PM

To Barbara A Kohn/MD/APHIS/USDA
cc Ray M Flynn/CO/APHIS/USDA@USDA
Subject help from FL

I just talked to Tom Holt, state vet in FL about an issue we're working in FL.

In the course of that conversation, he repeated again how happy he was with the new guidelines and with the use of the stat pak. He has written such to Chester and verbally told him the same.

We talked about some of the concern for the new guidelines from some areas and I asked him about other states and what they thought.

He suggested that we might have someone on the agenda for the monthly National Assembly Conference Call. I understand that VS sets that up and it is for all of the state vets and is used to update them on issues or have brief discussions.

He said he would be happy to ask for 5 minutes or so on the agenda for someone from AC to give a brief summary of the new guidelines and how we were going to run the new test. I told him I'd check with HQ and let him know but that I thought it was a good idea. I think either of us could easily do a 5 minute summary of the high points and in doing so get some feed back from state vets. I think they are going to be our biggest advocates in this.

What do you think?

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Barbara A
Kohn/MD/APHIS/USDA
05/21/2009 09:28 AM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: State Veterinarian and Area Veterinarians in Charge Ltr. and 2008 Guidance Update

Will do...probably early afternoon today...

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
05/21/2009 09:19 AM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject Re: State Veterinarian and Area Veterinarians in Charge Ltr. and 2008 Guidance Update

It does help if I'm on the cc list. That way I know when things are sent and to whom so I can answer questions about it from the field.
I think to be safe we should just send it again and see if it goes through.
The alternative would be to send a note to all state vets and see if they got it but probably easier to just resend. I don't think AVICs need it again. Plenty of response from them.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care
Barbara A Kohn/MD/APHIS/USDA



Barbara A
Kohn/MD/APHIS/USDA
05/21/2009 06:25 AM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc
Subject State Veterinarian and Area Veterinarians in Charge Ltr. and 2008 Guidance Update

Denise - I though you had been on the cc list...guess not - we wanted to make sure Betty and Bob were included, guess Joyce didn't pick up on it. You can see the lists it was sent out to...

Like I said, we can resend this with a "Please Read This" statement in the subject.

Barb

----- Forwarded by Barbara A Kohn/MD/APHIS/USDA on 05/21/2009 08:24 AM -----



Joyce L
Barkley/MD/APHIS/USDA
04/27/2009 04:17 PM

To VS ER State Vets All, VS ER State Vets North, VS WR State Vets All, VS WR AVIC, VS ER AVIC
cc Robert M Gibbens/CO/APHIS/USDA@USDA, Betty J Goldentyer/NC/APHIS/USDA@USDA
Subject State Veterinarian and Area Veterinarians in Charge Ltr. and 2008 Guidance Update



[attachment "st.vt_avic.pdf" deleted by Barbara A Kohn/MD/APHIS/USDA] [attachment "State.vet enclosure.TB Guidelines Oct 29 2008 final.doc" deleted by Barbara A Kohn/MD/APHIS/USDA]

Joyce Barkley
Secretary
Animal Care
PH: 301-734-7833
FX: 301-734-4978



Barbara A
Kohn/MD/APHIS/USDA
05/21/2009 08:25 AM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc

Subject State Veterinarian and Area Veterinarians in Charge Ltr. and
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2008 Guidance Update



st.vt_avic.pdf State.vet enclosure.TB Guidelines Oct 29 2008 final.doc

Joyce Barkley
Secretary
Animal Care
PH: 301-734-7833
FX: 301-734-4978



Barbara A
Kohn/MD/APHIS/USDA
05/21/2009 08:21 AM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: state vets 

I know Joyce sent it to all. She is at a training session this morning, but i will double check. We can obviously send it out to State vets again. Since we sent the link to the guidelines, it shouldn't be that anything bounced because of size.....I know I did a spot check on the "details" of the group on Lotus notes, and it was populated with state vets....Maybe we need to change the subject line to make it stand out....

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
05/20/2009 05:13 PM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject state vets

Hey Barb,

I think we need to check with whoever did the send on the letter to AVICs and State Vets and make sure the State Vets were on the list. I've gotten feed back from AVICs but none from State Vets and I've checked with a couple and they didn't get anything. I took their address right out of the address book.

We need to make sure they get the letter and the guidelines.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Barbara A
Kohn/MD/APHIS/USDA
05/15/2009 02:50 PM

To Denise M Sofranko/NM/APHIS/USDA, Tracy L
Bowman/MD/APHIS/USDA, James M
Tuck/MD/APHIS/USDA

cc

bcc

Subject Redo - see changes under testing options, last set of bullets
under each option



New Protocols after AZA.doc



Barbara A
Kohn/MD/APHIS/USDA
05/15/2009 01:44 PM

To Denise M Sofranko/NM/APHIS/USDA, Tracy L
Bowman/MD/APHIS/USDA, James M
Tuck/MD/APHIS/USDA

cc

bcc

Subject First Draft - certifying protocols and other information

Denise and Tracy -

can you review and comment. I think the organization is OK, but it covers many things....

Mike -

Does this jibe with what we discussed earlier regarding the letter?

Barb



New Protocols after AZA.doc

Certification of Accredited, Licensed Attending Veterinarians to use Elephant TB Stat-Pak®

Eligibility:

- Must be attending or consulting veterinarian for Animal Welfare Act licensed holder of elephants
- Must be licensed in the State where test is to be performed
- Must be accredited by APHIS under the **National Veterinary Accreditation Program (NVAP)**
- Information on the accreditation requirements can be found at http://www.aphis.usda.gov/animal_health/vet_accreditation/apply.shtml

Certification to order and run Stat-Pak:

Animal Care, in cooperation with Chembio Diagnostics, will provide training and certification in one of two ways.

Training at NVSL

- APHIS will provide space and elephant specialist for training course
- Training course will be 1 day in length
- Fee, paid to Chembio, will cover the cost of the Chembio trainer and test kits used (Fee to be determined based on number of participants)
- Accredited veterinarians (or licensees) will pay own travel, lodging, food, etc., costs
- Once certified, the accredited veterinarian can order test kits from Chembio

Training on site

- During the first year of the program, APHIS certified veterinarians will be at the facility to monitor the blood draws and run the Stat-Pak test
- Given sufficient prior notice and compatibility of schedules, APHIS can provide training to the attending veterinarian (accredited and licensed) so that he/she can order test kits after that time. To be consistent, this would be a 1 day training session, to include the representative from Animal Care, NVSL, or Chembio
- This option would involve no additional cost to the licensee, except the cost to bring in the Chembio representative (direct pay to Chembio), if needed

Testing Options:

If a facility decides that it does not want to have the attending veterinarian certified for this test, there are two options for testing.

APHIS, Animal Care oversight

- In cooperation with the licensee, Animal Care will provide a certified Federal veterinarian and other personnel needed to monitor the animal identification, blood drawing of the animal
- The Federal veterinarian will perform the test on site and record the results
- If the licensee prefers to send the blood sample to NVSL for testing, the Federal veterinarian or other representative will oversee the packaging and shipping of the sample(s) in order to maintain chain of custody to prevent any misidentification of samples

No On-site testing; Animal Care oversight

- If preferred by the licensee, samples may be drawn by the attending veterinarian or handler and submitted by the attending veterinarian to NVSL for analysis
- Animal Care must still positively identify the animals and oversee the blood draws. Chain of custody of the samples will be maintained

If the facility has a certified accredited veterinarian, for the official annual test, there are two options for testing.

APHIS, Animal Care monitored

- In cooperation with the licensee, Animal Care will provide a certified Federal veterinarian and other personnel (trained inspector) needed to monitor the animal identification, blood drawing of the animal
- The certified accredited veterinarian will perform the test on site and record the results. Animal Care will certify the recordkeeping

No On-site testing; Animal Care oversight

- If the licensee prefers to send the blood sample to NVSL for testing, the Federal veterinarian or ACI will oversee the packaging and shipping of the sample(s) in order to maintain chain of custody to prevent any misidentification of samples

- If preferred by the licensee, samples may be drawn by the attending veterinarian or handler and submitted by the attending veterinarian to NVSL for analysis
- Animal Care must still positively identify the animals and oversee the blood draws. Chain of custody of the samples will be maintained

Test Kit Licensing Requirements:

- Based on the licensing restrictions for the Elephant TB Stat-Pak®, the kit can only be ordered and performed by a approved laboratory
- At this time, NVSL is the only approved laboratory in the US
- Certified Federal (Animal Care) veterinarians will be authorized as approved laboratories
- Certified accredited, licensed attending veterinarians (accredited under the National Veterinary Accreditation Program, licensed in the State in which the test is to be performed) will be authorized to buy and used the test kits, but the official annual test must be run under the supervision of a certified Federal veterinarian or other Animal Care inspector
- Chembio will maintain a list of kits sold and provide that list to APHIS (this is needed to assure compliance with other TB testing and surveillance programs)
- For parties that want APHIS to run the test animal-side, procedures will be in place for the ordering and payment for the test kits by the facility through NVSL

Summary/Outline of the PROGRAM:

First year of the new testing program:

- Animal Care will provide personnel to provide positive identification of each animal, notations of which animals are or are not tested that day, observe the blood draw, maintain chain of custody/positive identification of samples, and run the test (certified Federal veterinarian) and record the results. During this process, Animal Care will also observe and discuss trunk washes.
- As requested by the facility, the accredited attending veterinarian may be trained and certified at this time.
- The facility is responsible for providing all necessary personnel for handling the animals, drawing the samples, for all supplies needed for the drawing and labeling of the samples.
- If the facility has a certified accredited licensed attending veterinarian, that person can run the tests, but an Animal Care certified veterinarian and other Animal Care personnel, as needed, will monitor and oversee the testing.

Subsequent years:

- Facility can perform the official testing on site under the oversight of a certified Animal Care inspector
- Facility can have Animal Care perform the animal-side test (certified Federal veterinarian)
- Facility can draw blood and send it to NVSL (animals identified and process monitored by a certified Animal Care inspector)
- Facility can draw blood and sent to foreign laboratory ONLY with the proper US Fish and Wildlife permit (export permit for endangered species)

Federal veterinarians and inspectors:

- If the Stat-Pak test is to be run by Animal Care, it must be run by a certified Federal veterinarian in order to meet the requirements of the kit license and possibly many State Practice Acts regarding duties performed by a veterinarian.
- If Animal Care is there to monitor the process only (so that it will be considered the official test), the AC representative (trained and certified veterinarian or, possibly, a non-veterinarian inspector) will positively identify the animals, certify the record sheet, and/or maintain chain of custody of an official test for samples being shipped.



Barbara A
Kohn/MD/APHIS/USDA
05/14/2009 09:33 AM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: mou with chem bio 

This is a good idea. We need to formalize it for our and ChemBio's protection....Is there anything else we need to be sure to include in the agreement? I can start a list and talk with contracts and grants....The key is to try and run it by CVB to be sure we are not violating licensing requirements.

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
05/13/2009 05:29 PM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject mou with chem bio 

Hey Barb,

I've been thinking about this agreement with Chem Bio (and not just since today) where they'll give us names and numbers of anyone buying tests from them and I wonder if we should have it in some sort of "legal" language rather than just a note between Konstantin and me, which is kind of where it is right now. I'm not comfortable coming up with the wording on my own. So are there people within APHIS who normally do contracts that could put something together or should we run it by OGC or someone in the Administrator's office?

Thoughts welcome.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Barbara A
Kohn/MD/APHIS/USDA
04/17/2009 01:09 PM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: letter to USAHA

So, for us, it is all ready to go (I saw the signed letters to USAHA - just some grammar tightening- and to the State Vets and AVICs) - just need to have the other USAHA letter about HP done.....What a pain. I am hoping that next Wednesday (I am in the office) it may be ready and we can go by the need of the week. I will also be sending Tricia the e-copy of the guidelines and have that ready to go by Wed or Thurs. Tricia is still out - good news the ankle is not broken, bad news, because of other medical conditions, it needs to be treated as such, with at least 2 weeks in bed with ice and elevation of the ankle.

Only about half of my hair is pulled out!

B,
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
04/17/2009 01:04 PM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject Re: letter to USAHA

One other nice glitch in all of this. I'm supposed to talk about the new guidelines at the PAWS conference next Saturday. If we don't let anyone know about this before then, it will be awkward to say the least, to make the initial announcement at PAWS. I hate to have to redo my presentation at this point but I don't feel comfortable with the one I have if it's not official yet.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care
Barbara A Kohn/MD/APHIS/USDA



Barbara A
Kohn/MD/APHIS/USDA
04/17/2009 08:20 AM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc
Subject Re: letter to USAHA

Well....Andy and/or Chester decided that, after having the letter for a week and a half, that they want to rewrite it a little. In addition, they want the elephant letter and the HP letter to USAHA to go out together...Problem is, the HP letter hasn't been written yet. Tracy is going to sit with Rachel on Tuesday to get it written. Looks like the USAHA letter won't go out until end of next week. I just learned this this AM and my frustration level is sky-high. However, Tracy says to just roll with it (we can't change it anyway), and she remains a driving force to get this out....

I guess maybe any letter to the committee/consultants would need to indicate that we foresee implementation, but that the formal letter to USAHA is in clearance???? Or, if it would be better, to hold off til late next week....

Arrrgggghhhh!!!

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
04/17/2009 10:12 AM

To Barbara A Kohn/MD/APHIS/USDA
cc

Subject letter to USAHA

Hey Barb,

I'd like to get the letter to the subcommittee out today if I can. Its just the one from me thanking them for their work and giving them notice that we're accepting the guidelines. I don't want to send it before the USAHA one goes out though.

Could you let me know when that happens? We also need a copy to go to RDs.

thanks!

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Barbara A
Kohn/MD/APHIS/USDA
04/17/2009 10:20 AM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: letter to USAHA 

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Arrrgggghhhhhh!!!

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
04/17/2009 10:12 AM

To Barbara A Kohn/MD/APHIS/USDA
cc
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Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Barbara A
Kohn/MD/APHIS/USDA
04/16/2009 01:49 PM

To Denise M Sofranko/NM/APHIS/USDA
cc Tracy L Bowman/MD/APHIS/USDA@USDA
bcc
Subject Roles and Responsibilities

Here you go - these should have the edits we discussed this AM. These are documents we thought to run by the RDs before we finalize and get sent out.

Barb



Draft dear licensee letter statpak 2009.doc Responsibilities and Roles.doc AC Employees Elephant TB notify.doc

Elephant TB Stat-Pak® Protocol for 2009-2010 (Year 1)

Project Managers (PM):	Denise Sofranko	Barbara Kohn
Certified VMOs (CV):	Jeff Baker Susan Brunkhorst Cindy DiGesauldo Paula Gladue Tami Howard Mary Moore Jaime Niemann	Nicolette Petervary Debra Sime Mike Smith Tracy Thompson Michelle Williams Nadira Williams Kate Ziegerer
	Denise Sofranko*	Greg Gaj**

Person in Charge of Testing on site: Certified Veterinarian (CV)

Home Inspectors = HI

* Denise is a PM and will also be CV at some facilities

** Greg will be involved in some FL facility tests, but not outside state

Event	Person Responsible
1. CV assigned to specific licensees 1a. Table of HI and CV will be included in notification in 2.	PM
2. HI and SACS notified of TB testing program and assignments	HQ will send memos
3. HI talks with CV to discuss testing and contact with facility	HI
4. HI calls facility to discuss timing of regular annual trunk washes and the need to coordinate this with the new testing. 4a. Discuss dates of regular testing and possible other dates convenient to the facility 4b. Inform facility of the list of supplies that must be available for testing (There will be a handout listing these) 4c. Inform facility how to order the test kits and how they will be delivered (There will be a handout outlining the process) 4d. Determine names and number of elephants that will be on site during testing, and determine if the Stat Pak test will be performed on site or sent to NVSL.	HI
5. HI send info on possible testing dates to CV	HI

6. CV, in consultation with Dr. Sofranko (if needed), determines which facilities will need additional AC personnel and how many 6a. CV inform Dr. Sofranko of possible testing dates	CV
7. CV contacts SACS (their own) with possible testing schedule 7a. CV contacts facility SACS to discuss any extra help needed	CV
8. SACS OKs CV time for testing (travel and testing)	SACS
9. SACS contacts field inspectors near facility that needs extra AC personnel for testing. Relay information regarding location and CV to contact for details	SACS
10. At least 1 month prior to scheduled testing date, facility must contact NVSL to order test kits and to pay for test kits. Facility must order 1 kit per elephant. If no payment received by NVSL at least 2 weeks prior to the scheduled date, the testing must be cancelled and rescheduled. No testing without pre-payment.	Facility, CV
11. Test kits will be shipped from ChemBio to the CV only.	ChemBio, CV
12. At least 2 weeks before testing, CV and HI to determine hotel arrangements. Inform AC inspectors of hotel and meeting arrangements	CV and HI
13. The PM will provide CV with a list of elephants to be tested at each facility. The CV will prefill report form to include all elephants (at least 3 copies needed – 1 left at facility, 1 to RO, one to Dr. Kohn)	PM CV
14. Positive ID of elephants	HI and AC insp
15. Observation of Trunk Wash	CV and HI
16. Observation of each blood draw	HI or AC insp
17. Running and recording test results	CV
18. If needed, labeling, packaging, shipping of MAPIA samples 18a. Facility must supply shipping label (paid, 3 rd party) or pay at shipping desk 18b. Chain of custody maintained. In AC possession until in possession of shipping company	CV Facility AC personnel
19. If needed, labeling, packaging, shipping of Stat-Pak samples to NVSL (HI will get the initial information during first contact with licensee) 19a. Facility must supply shipping label (paid, 3 rd party) or pay at shipping desk 19b. Chain of custody maintained. In AC possession until in possession of shipping company	CV/HI Facility AC personnel



United States
Department of
Agriculture

Animal and Plant
Health Inspection
Service

Animal Care –
Eastern Region

920 Main Campus
Drive, Suite 200

Raleigh, NC 27606

919-855-7100

OR

2150 Center Avenue
Building B

Fort Collins, CO
80525

970-494-7478

Dear Licensees with Elephants:

The Animal and Plant Health Inspection Service (APHIS) has required the testing of elephants for tuberculosis (TB) since 1998, as specified in the "Guidelines for the Control of Tuberculosis in Elephants." This document, written by the National Tuberculosis Working Group for Zoo and Wildlife Species, has been updated several times since 1998. In October 2008, the United States Animal Health Association approved the most current updates to this document and requested that APHIS adopt this updated version.

APHIS has adopted this most recent approved version of the Guidelines, and they can be found on our website (www.aphis.usda.gov/animal_welfare/) under Publications and Reports. We have also enclosed a printed copy of the Guidelines.

The Guidelines incorporate a new blood test, the Elephant TB Stat-Pak®, in addition to the current trunk wash protocol. APHIS will implement this new requirement beginning March 2010; facilities must accomplish this new testing protocol prior to January 31, 2011. Testing the first year must be done under the direct supervision (blood draw) of a Federal AC veterinarian, with the Federal veterinarian either performing the test him/herself, or supervising the handling, packing, and shipping of the samples to the National Veterinary Services Laboratory. Enclosed is a document that outlines the roles and responsibilities of the licensee.

All AC veterinarians responsible for overseeing the new test will be trained prior to the March 2010 implementation date. State veterinarians have been issued an invitation to observe this new protocol, and may be in attendance when testing occurs at your facility. During the official testing, APHIS will review and observe your trunk wash protocols to detect any collecting, handling, and shipping errors that could result in invalid tests. After the first year of testing, AC will evaluate the program and consider changes in the oversight process.

We appreciate your support of these new procedures and will be happy to answer any questions you might have regarding the protocol outlined above. Please contact my office if there are any further questions about this new process.

Sincerely,

Regional Director
Animal Care

Enclosure



Safeguarding American Agriculture

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1-800-877-8339

Roles and Responsibilities for Licensees

1. Discuss normal testing date(s) when contacted by your home inspector. Work with Animal Care in determining a mutually agreed upon date for new testing and trunk wash. Determine if Animal Care (AC) will run the test on site, or if the collected blood will be sent to the National Veterinary Services Laboratory (NVSL) to test. If blood samples will be sent to NVSL, facility must provide appropriate packing and shipping materials.
2. At least 1 month prior to scheduled testing date, the licensee/facility will contact NVSL to order and pay for test kits (one kit per elephant to be tested). If no payment received by NVSL at least 2 weeks prior to the scheduled testing date, the testing must be cancelled and rescheduled. No testing without pre-payment.
3. Test kits will be shipped from ChemBio to the AC certified veterinarian (testing veterinarian) only.
4. The licensee/facility is responsible for having sufficient experienced handler to perform the required blood collection and trunk wash on each animal. The licensee/facility will also provide sufficient supplies to perform the required test, including blood collection tubes, needles, syringes, etc.
5. If the Stat-Pak test is positive, a MAPIA test must be performed by Chem Bio. The blood sample collected for the Stat-Pak will be used if there is a sufficient quantity. If not, another blood sample must be obtained under AC supervision. The licensee/facility must supply shipping label (paid, 3rd party) or pay at shipping desk. Chain of custody of the sample must be maintained by AC. The sample will be in AC possession until it is in the possession of shipping company.
6. If the licensee elects to send the collected sample to NVSL for Stat-Pak testing, the facility must have all needed, labeling, packaging, shipping supplies needed to send sample to NVSL. Facility must supply shipping label (paid, 3rd party) or pay at shipping desk. Chain of custody of the sample must be maintained by AC. The sample will be in AC possession until it is in the possession of shipping company.



United States
Department of
Agriculture

Animal and Plant
Health Inspection
Service

4700 River Road
Riverdale, MD
20737

Date:

To: All Animal Care (AC) Employees

From: Chester Gipson, Deputy Administrator
Animal Care

Re: New Elephant Tuberculosis (TB) Testing Guidelines

AC is implementing the new TB guidelines for elephants that were approved by USAHA in October 2008. This document can be found on our website at (http://www.aphis.usda.gov/animal_welfare/downloads/elephant/elephant_tb.pdf). AC has developed a protocol for the new testing requirements, including the direct oversight of the blood test by trained, certified Veterinary Medical Officers (VMOs) and review of trunk wash procedures. A certified VMO (CV) will oversee the on-site testing of each facility, but the home inspector will be involved in the testing process, including facilitating the scheduling of the testing. AC must make a positive identification of each elephant, observe the drawing of blood from each elephant (or noting if the elephant cannot be bled by facility personnel), perform the test, and record the test results. The home inspectors and CVs will work together to arrange the testing. The CV will be responsible for the testing at the assigned elephant facility. Other inspectors may be called upon to help at the larger facilities. SACS will help to coordinate the scheduling of testing and extra inspectors to help out. AC will evaluate the need for continued direct oversight after the first year of testing.

Training and certification of selected AC VMOs (CVs) will take place in January/February 2010, and we will start the testing in or around March 2010. A CV will be assigned to each facility holding elephants. The home inspectors for these facilities should work with the CV and the licensees to schedule the testing of the elephants. We are allowing a year to complete this testing, timing it to coincide with scheduled trunk washes.

AC has contacted the State veterinarians and the VS Area Veterinarians in Charge to ensure that all parties are aware of our activities. The guidelines have been posted on the website, and a Frequently Asked Questions (FAQ) document will be posted shortly.

For your information, we have attached the documents: the letter sent to licensees, and the letter to the State Veterinarians and AVICs. If you are the home inspector for any elephant facility, you will be provided with the name of your CV soon. If you have any questions, please contact your SACS, Dr. Denise Sofranko (Field Specialist for Elephants) or Dr. Barbara Kohn (Staff Veterinarian for Exhibition Animals).

Attachments



Safeguarding American Agriculture

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Federal Relay Service
(Voice/TTY/ASCII/Spanish)
1-800-877-8339



Barbara A
Kohn/MD/APHIS/USDA
04/16/2009 09:31 AM

To Denise M Sofranko/NM/APHIS/USDA, Tracy L
Bowman/MD/APHIS/USDA
cc
bcc

Subject Letter to elephant licensees - updated

Denise -

here is the dear licensee letter, edited to reflect the attachments and with some other wording changes. Is this OK. Do we want to (in the last paragraph) add that they should also contact the Regional office to start scheduling facility visits? I think it may be too soon for that, but willing to consider it.

Barb



Draft dear licensee letter statpak 2009.doc

Will call after 10 my time!



Barbara A
Kohn/MD/APHIS/USDA
04/16/2009 09:15 AM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc

Subject Re: letter to licensees 

I am all for keeping things simple. Hoping to get the letter to States and AVICs out tomorrow. Let's talk later about the letter to USAHA and what is going on here. Shouldn't be put in print right now... Anyway - the flow chart is in the combined document. It is a Visio file so I did not send it separately as most do not have Visio on their computers (it is a graphics package for office suite that make flow charting a little easier). I have attached it below as a word document (I hope). That being said, I think the list of responsibilities would be more appropriate. Will amend the licensee letter.

I am attending Laurie's marine mammal talk today from noon-2 my time....won't be answering phones or e-mails during that time.

Barb



flowchart.doc The chart would have to be updated to use, as the arrangements for the test kits has changed (going through NVSL now)
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
04/15/2009 05:51 PM

To Barbara A Kohn/MD/APHIS/USDA
cc

Subject letter to licensees

In the current draft to the licensees, it mentions the flow chart. I can't find that anywhere. Have we ditched that from the list? My preference would be to send licensees the letter with the guidelines and the roles and responsibilities attachments. Keep it simple.

Inspectors get the guidelines and roles and responsibilities (added this to what I was thinking earlier)

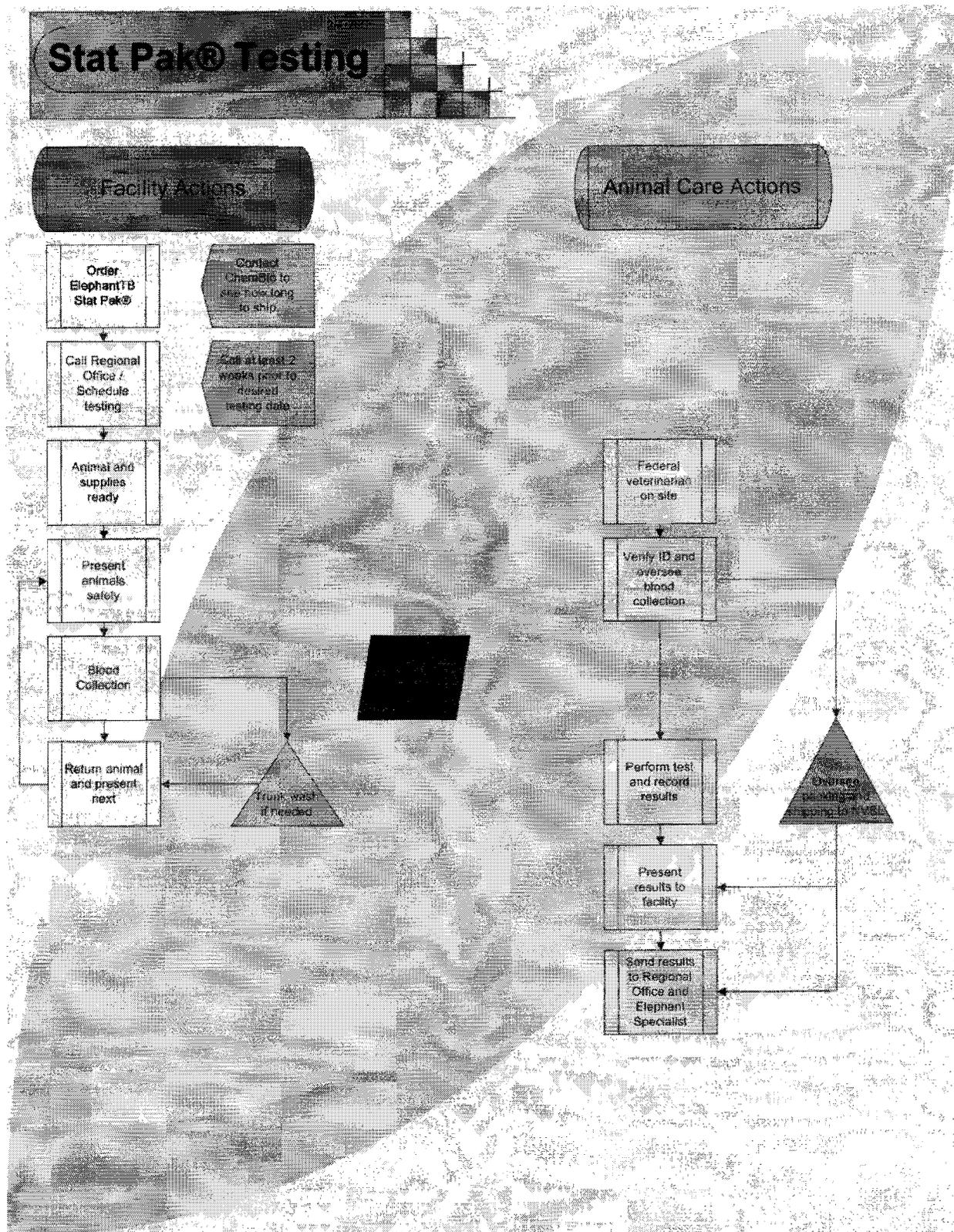
Testing team gets packet of attachments

State vets and AVICs get guidelines

I've also asked Bob and Betty for opinions on who should call who on the testing schedule.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

Timeline/Flow Chart





Barbara A
Kohn/MD/APHIS/USDA
04/15/2009 01:32 PM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: letters to go out from region 

Good idea. Sorry for the delay, I was at lunch and then in a discussion with IT person.....Here are the letters as of now.

Barb



Letter to AC employees draft.doc Draft dear licensee letter statpak 2009.doc
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
04/15/2009 11:31 AM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject letters to go out from region

Barb,
I'm thinking maybe we should send the letter to the licensee and to the inspectors to the RDs now as a draft for their comment. I can include the guidelines. That way if there are any edits, they can get them in so we're ready to go on schedule.
What do you think?

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Barbara A
Kohn/MD/APHIS/USDA
04/14/2009 03:33 PM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject State Vet letter draft

Denise -

Can you take a look at this. Wanted to be clear but concise.....have at it!

Thanks.

Barb



Dear State Veterinarians and Area Veterinarians in Charge.doc



Barbara A
Kohn/MD/APHIS/USDA
03/26/2009 10:26 AM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: Fw: Elephant Testing Project

Thankfully, there have been no changes from the info Tracy gave me yesterday or in another e-mail. My rework of the training costs is for the persons listed!

I have to run an errand at noon and have a dentist appointment for one of my sons this afternoon so I am leaving at 1:30 today. As far as I know, I have no meetings tomorrow and will be in all day....

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
03/26/2009 10:23 AM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject Fw: Elephant Testing Project

ERO roster.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

----- Forwarded by Denise M Sofranko/NM/APHIS/USDA on 03/26/2009 08:25 AM -----



Betty J
Goldentyer/NC/APHIS/USDA
03/26/2009 07:19 AM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc
Subject Elephant Testing Project

The ER roster is set and you can go ahead and send out the information.
Susan Kingston, Susanne Brunkhorst, Tami Howard, Paula Gladue, Deb Sime, Greg Gaj and Nicolette Petervary.
They are all onboard and waiting to hear from you.
Betty



Barbara A
Kohn/MD/APHIS/USDA
03/23/2009 11:23 AM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: TB FAQ

That is a good idea, especially since LPA is suppose to be updating the website to include useful information and people are looking for!

I think we should also have a summary of what the TB testing requirements are - no one wants to read through the entire document...

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
03/23/2009 11:11 AM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject Re: TB FAQ

I wonder if we might want to post some FAQs of our own on our web site? I could work with some of the USAHA sub committee members to make sure they are accurate.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care
Barbara A Kohn/MD/APHIS/USDA



Barbara A
Kohn/MD/APHIS/USDA
03/23/2009 07:55 AM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc
Subject Re: TB FAQ

What planet has he been living on????
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
03/23/2009 09:51 AM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject TB FAQ

Just an interesting take on TB from Dennis

<http://www.elephantcenter.com/default.aspx?id=15854>

They used it as an exhibit in the trial.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Barbara A
Kohn/MD/APHIS/USDA
03/23/2009 09:55 AM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: TB FAQ 

What planet has he been living on????
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
03/23/2009 09:51 AM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject TB FAQ 

Just an interesting take on TB from Dennis

<http://www.elephantcenter.com/default.aspx?id=15854>

They used it as an exhibit in the trial.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Barbara A
Kohn/MD/APHIS/USDA
02/24/2009 03:38 PM

To Denise M Sofranko/NM/APHIS/USDA
cc Tracy L Bowman/MD/APHIS/USDA@USDA
bcc
Subject Re: Draft letter to Clifford - have at it...

Thanks, Denise. I will double check the spelling...caught some when I noticed words that were spelled correctly, but were not the right word....obviously didn't catch them all....Spell check doesn't stop if the letters spell a real word...

Yes, we can and should include ARD (does that stand for Ag Research Division?).

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
02/24/2009 03:33 PM

To Barbara A Kohn/MD/APHIS/USDA
cc Tracy L Bowman/MD/APHIS/USDA@USDA
Subject Re: Draft letter to Clifford - have at it...

Barb,

I think this looks good. A few typos but I'm sure you'll catch those in the final. ;-)
Do you want to include ARD in the list of folks meeting about this? Ray Waters has been instrumental in some of our discussions.
I like the default date for replying.

thanks!

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care
Barbara A Kohn/MD/APHIS/USDA



Barbara A
Kohn/MD/APHIS/USDA
02/24/2009 12:42 PM

To Tracy L Bowman/MD/APHIS/USDA@USDA, Denise M Sofranko/NM/APHIS/USDA@USDA
cc
Subject Draft letter to Clifford - have at it...

Tracy -

As requested, here is draft language for a letter from Chester to John. We would include a copy of our document package with the letter. Do we want this as a letter, or drafted as a decision memo, so we can just get a copy back that hopefully says "concur". The body of the test can go into either format, so I need to know what format to use when we finalize a draft (now that is an oxymoron!).

Thanks.

Barb

Animal Care has been monitoring the tuberculosis status of the national elephant herd since 1998, under the authority of the Animal Welfare Act. We have implemented a monitoring and treatment program based on the guidelines provided by the National Tuberculosis Working Group for Zoo & Wildlife Species. This guidance document has been amended several times since its first publication. The most recent amendments to this document have been approved by the US Animal Health Association (USAHA). The USAHA has recommended that Animal Care adopt and implement the 2008 amended document.

In anticipation of this recommendation, Animal Care has been meeting with representatives of the National Veterinary Services Laboratory, Veterinary Services, and the Center for Veterinary Biologics in order to address the issue of a recently licensed antemortem blood test for tuberculosis screening in elephants, the use of which is important to the implementation of the newly approved guidelines. This collaboration has resulted in a consensus document that addresses the issues around the use of this new technology/test. It was agreed that Animal Care would develop a specific protocol for the use of the Chembio ElephantTB Stat-Pak®, while the parties agreed in principle to the use of the newly licensed test by accredited veterinarians for other testing purposes, similar to the use of other TB tests by accredited veterinarians. Animal Care would implement a protocol for official testing in elephants to meet the recommendations of the new guidelines.

Animal Care has developed a protocol for official testing of elephants which will allow for positive identification of all elephants tested, collection of results, and Federal veterinarian performance of the test. Per the guidelines, the gold standard of trunk wash with culture and sensitivity remains as a major component of the testing regime, to be augmented with the ElephantTB Stat-Pak®.

For your information, enclosed is the background information on the testing of elephants for TB under the Animal Welfare Act, as well as a protocol for the new test. We know your staff has been keeping you apprised of the activity around these guidelines for elephants. Animal Care wants to make sure Veterinary Services is aware of our protocol procedures and our need to implement these new guidelines and testing by June 2009, to ensure the health and well-being of the national elephant herd. Please feel free to review the information. Animal Care will move forward with the announcement of the new guidelines and testing protocols as planned by March 15, 2009, unless we are made aware of any major objections that may not have been addressed during our collaboration with VS, NVSL, and CVB representatives. We have had preliminary agreement from the parties involved in our year-long conversations about the guidelines and do not foresee any major problems at this time.

Thank you for your consideration.



Barbara A
Kohn/MD/APHIS/USDA
02/12/2009 02:50 PM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: Elephant TB guidelines implementation package

Let me ask Tricia when she gets back next week I think we may have a GIS program. I have map point on my laptop, but I do not know how to really use it. I can look into that. The RD's may know if we still have any facility distribution maps - I know if was analyzed at least several years ago and that they used it to redistribute facilities and locate positions.....

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
02/12/2009 02:47 PM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject Re: Elephant TB guidelines implementation package

I think it's all fine. I don't mind the travel so much. It will get me out to facilities I've never been too and let me see some I haven't seen in a while. And I can treat some of them as little mini training courses for inspectors.
I would probably be going to some of the bigger ones anyway.

I can start looking at this from a locational point to see about grouping facilities. Do you know if we have any sort of mapping program that would do that?

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care
Barbara A Kohn/MD/APHIS/USDA



Barbara A
Kohn/MD/APHIS/USDA
02/12/2009 12:43 PM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc
Subject Re: Elephant TB guidelines implementation package

Yes -

you may be a permanent airport fixture! At this point, the fewer facilities the better! I will see about the lists tomorrow, and try to remember to put the SACS on the other AC personnel to train...just didn't think about it today. I just feel that if we had planned to do face-to-face training, then we may have gotten a different response! Should be a lively discussion next week! I just asked Mike to get us on the agenda, so I don't know when it will be....I will let you know. May have to call you, but I think with the guys looking this over before hand, that shouldn't be necessary. I guess this may turn out to be a case of "be careful what you wish for!" :->

Time will tell....

B

Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
02/12/2009 02:37 PM

To Barbara A Kohn/MD/APHIS/USDA

cc

Subject Re: Elephant TB guidelines implementation package

I think I already took Shawver off. Maybe you got the list before I did that. (b)(6) elephant will probably going to Dallas soon. (b)(6) trying to sell his. (b)(6) has sold two of his and I'm guessing the third is not far behind as he is in reportedly bad health. the one with no animals is Dawn animal agency and I left it blank because I don't know anything about the elephant. They might have a waiver to not test because the owner isn't able to handle. That also means probably not blood test so we might not even bother with that one. Although, why she is still allowed to keep it is another issue.

I'm thinking I may be a traveling fool this year. ;-)

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care
Barbara A Kohn/MD/APHIS/USDA



Barbara A
Kohn/MD/APHIS/USDA
02/12/2009 12:33 PM

To Denise M Sofranko/NM/APHIS/USDA@USDA

cc

Subject Re: Elephant TB guidelines implementation package

OK - which facilities are not active. I just counted up the ones on the list...there was only one with no animals listed (maybe 2 but I think the second does have elephants, If the animal from Shawver is transferred, that could eliminate her....who else?

Thanks,

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
02/12/2009 02:31 PM

To Robert M Gibbens/CO/APHIS/USDA@USDA

cc Barbara A Kohn/MD/APHIS/USDA@USDA, Betty J
Goldentyer/NC/APHIS/USDA@USDA, Tracy L
Bowman/MD/APHIS/USDA@USDA



Subject Re: Elephant TB guidelines implementation package 

fyi: there are 114 facilities with elephants. One of those will be going away soon with another possibly giving up their elephants.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care
Robert M Gibbens/CO/APHIS/USDA



Robert M
Gibbens/CO/APHIS/USDA
02/12/2009 12:21 PM

To Tracy L Bowman/MD/APHIS/USDA@USDA
cc Barbara A Kohn/MD/APHIS/USDA@USDA, Betty J
Goldentyer/NC/APHIS/USDA@USDA, Denise M
Sofranko/NM/APHIS/USDA@USDA
Subject Re: Elephant TB guidelines implementation package 

Okay - you get the blame. ☺

I understand the budgetary constraints, but I view it this way; if we're expecting our VMOs to do hands-on work in the plain view of the regulated community (i.e., handle blood samples and run blood tests), we need them to be comfortable and competent with the equipment and procedures. In my view, distance learning is not an effective training method for this type of hands-on procedure, especially considering that our VMOs may have never done tests like this before (or at least not recently). Another option we could consider if face-to-face training of a large number of VMOs is not viable, is minimizing the number of VMOs who will actually run the tests.

Tracy L Bowman/MD/APHIS/USDA



Tracy L
Bowman/MD/APHIS/USDA
02/12/2009 12:09 PM

To Barbara A Kohn/MD/APHIS/USDA@USDA
cc Betty J Goldentyer/NC/APHIS/USDA@USDA, Denise M
Sofranko/NM/APHIS/USDA@USDA, Robert M
Gibbens/CO/APHIS/USDA@USDA
Subject Re: Elephant TB guidelines implementation package 

I know that face to face training is the best approach for something like this, but I also know that \$\$ are constrained and we are under pressure to reduce travel costs.....so I asked Denise and Barb to consider whether we might be able to do this training via distance learning.

It would seem that maybe we all concur that this might be an arena where face to face training really is the right way to go.....but I wanted you to know that it was me that pushed them in the direction they went.

Tracy Bowman
Acting Assistant Deputy Administrator
Animal Care
Desk Phone: 301-734-6328
Fax: 301-734-4978
Cell Phone: (b)(6)

Barbara A Kohn/MD/APHIS/USDA



Barbara A
Kohn/MD/APHIS/USDA
02/12/2009 02:03 PM

To: Denise M Sofranko/NM/APHIS/USDA@USDA
cc: Betty J Goldentyer/NC/APHIS/USDA@USDA, Robert M
Gibbens/CO/APHIS/USDA@USDA, Tracy L
Bowman/MD/APHIS/USDA@USDA
Subject: Re: Elephant TB guidelines implementation package

Yes, about the accredited vet thing. We have had many discussions with VS and the requirement of accreditation is pushed by them to make sure they have some leverage regarding fraudulent and inappropriate use of the tests.

As for the training, I think I can speak for Denise as well - we are all for face to face but were not counting on it as any type of certainty because of current training positions by the ACMT. Because each test used is 200 dollars, it is not likely that everyone gets to perform a test. Denise and I also discussed having ChemBio involved in the training for the same reasons discussed - credibility for our VMOs and SACS....

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
02/12/2009 01:52 PM

To: Robert M Gibbens/CO/APHIS/USDA@USDA
cc: Barbara.A.Kohn@aphis.usda.gov, Betty J
Goldentyer/NC/APHIS/USDA@USDA, Tracy L
Bowman/MD/APHIS/USDA@USDA
Subject: Re: Elephant TB guidelines implementation package

I think most of the attending vets are accredited. There may be some of the bigger facilities where they all aren't but at least one would be. Most of the traveling exhibitors have AVs who write their health certs. and I think they are all accredited.

This was put in as a response to some concerns from VS that arose at the mtg. last year in Ames.

If we do find that some of the AVs are not accredited, we might have to rethink this..

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care
Robert M Gibbens/CO/APHIS/USDA



Robert M
Gibbens/CO/APHIS/USDA
02/12/2009 11:44 AM

To Barbara.A.Kohn@aphis.usda.gov
cc Betty J Goldentyer/NC/APHIS/USDA@USDA, Denise M
Sofranko/NM/APHIS/USDA@USDA, Tracy L
Bowman/MD/APHIS/USDA@USDA
Subject Re: Elephant TB guidelines implementation package 

One question and on comment.

Question (or confirmation): it appears from the statement below that only accredited vets can order the test kits. It seems like a problem to place this limitation on ordering, as it could make access to the test kits difficult for the elephant exhibitors (since many AV's are not accredited)? (note: I'm sure y'all have already addressed this)

The facility is responsible for having an adequate number of ElephantTB Stat Pak® test kits on site to accommodate the testing of all resident animals. Test kits are available from the ChemBio Diagnostic Systems, Inc., Medford, New York. The test kits must be ordered by the "accredited" attending veterinarian.

Comment

I think if we're going to have our VMOs be confident they are doing things correctly, there has to be face-to-face training. It doesn't have to be an all hands meeting, it could be a train the trainer approach. A webinar alone will be insufficient for many VMOs. If we have VMOs that appear unsure of what they are doing, our credibility could take a serious hit.

Barbara A Kohn/MD/APHIS/USDA



Barbara A
Kohn/MD/APHIS/USDA
02/12/2009 11:27 AM

To Denise M Sofranko/NM/APHIS/USDA@USDA, Robert M
Gibbens/CO/APHIS/USDA@USDA, Betty J
Goldentyer/NC/APHIS/USDA@USDA, Tracy L
Bowman/MD/APHIS/USDA@USDA
cc
Subject Elephant TB guidelines implementation package

Denise and I have been working to put together a package to discuss at the ACMT meeting next week to implement the USAHA approved guidelines for TB testing and treatment in elephants. The new guidelines incorporate the new Stat-Pak test by Chem Bio. Please take a look at the document package to see if there are any glaring problems with the information and approach. The actual guidelines are not included (that would add another 30+ pages to the document). I will have printouts of the document, next week, as well as CD copies that you can take back with you (and leave the paper).

Thanks.

Barb

[attachment "Elephant TB testing Document all.doc" deleted by Robert M Gibbens/CO/APHIS/USDA]



Barbara A
Kohn/MD/APHIS/USDA
02/12/2009 01:43 PM

To Denise M Sofranko/NM/APHIS/USDA
cc Betty J Goldentyer/NC/APHIS/USDA@USDA, Robert M
Gibbens/CO/APHIS/USDA@USDA, Tracy L
Bowman/MD/APHIS/USDA@USDA
bcc
Subject Re: Elephant TB guidelines implementation package

Thanks, Denise - I forgot to mention the need to update the list....
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
02/12/2009 01:42 PM

To Barbara A Kohn/MD/APHIS/USDA
cc Betty J Goldentyer/NC/APHIS/USDA@USDA, Robert M
Gibbens/CO/APHIS/USDA@USDA, Tracy L
Bowman/MD/APHIS/USDA@USDA
Subject Re: Elephant TB guidelines implementation package

Fyi,

The list of elephant facilities should be accurate but the list of inspectors to be trained is not complete. I only listed the ones I was pretty sure of. I am still waiting for the list of facilities with inspectors to complete the list of trainees. It should probably also include the SACS. Hope to have it finished by the meeting.

thanks!

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care
Barbara A Kohn/MD/APHIS/USDA



Barbara A
Kohn/MD/APHIS/USDA
02/12/2009 11:27 AM

To Denise M Sofranko/NM/APHIS/USDA@USDA, Robert M
Gibbens/CO/APHIS/USDA@USDA, Betty J
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Barb



Barbara A
Kohn/MD/APHIS/USDA
02/12/2009 01:27 PM

To Denise M Sofranko/NM/APHIS/USDA@USDA, Robert M
Gibbens/CO/APHIS/USDA@USDA, Betty J
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cc

bcc

Subject Elephant TB guidelines implementation package

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Thanks.

Barb

[attachment "Elephant TB testing Document all.doc" deleted by Barbara A Kohn/MD/APHIS/USDA]



Barbara A
Kohn/MD/APHIS/USDA
02/10/2009 01:24 PM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: Blockbuster hit - Elephant document!

Will review the grammar and spelling and maybe clean up format but you have done the bulk of it!
Thanks,
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
02/10/2009 01:23 PM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject Re: Blockbuster hit - Elephant document!

Probably could use some cleaning up but wanted to get it started so we aren't slammed at the end of the week.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care
Barbara A Kohn/MD/APHIS/USDA



Barbara A
Kohn/MD/APHIS/USDA
02/10/2009 11:21 AM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc
Subject Re: Blockbuster hit - Elephant document!

Thanks, Denise. I haven't been able to get to this yet...one of those days. Looks OK to me. I will add it to the growing document.....

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
02/10/2009 01:09 PM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject Re: Blockbuster hit - Elephant document!

Here's some information added to the table.

There is a group 5 in the new guidelines. My misreading.

Denise M. Sofranko, DVM
 Field Specialist for Elephants
 USDA/APHIS/Animal Care
 Barbara A Kohn/MD/APHIS/USDA



Barbara A
 Kohn/MD/APHIS/USDA
 02/10/2009 08:48 AM

To Denise M Sofranko/NM/APHIS/USDA@USDA
 cc
 Subject Re: Blockbuster hit - Elephant document!

Denise -

I think your summary is a fine 1st run through. I was thinking of putting the information into a table like the one below. General categories, summary of differences, and notes about what it means to the inspector and Regional offices. I can take your document and give it a go, or feel free to try it...I will work on it this afternoon, I hope. I will also go through your comments on the entire set of documents this afternoon as well.

I did hear back from FWS - apparently there is a special rule for African elephants, and they apparently don't need the permit/notice that the Asians do. The "owner" was or is with Animal Actors of Hollywood, according to FWS. They had not been informed. The good news, apparently, is that we will not get enmeshed with an ESA case!

Will be in touch.

Barb

Topic	Old Guidelines	New Guidelines
Definitions		Expanded
References		Expanded
Testing Requirements	Yearly trunk wash, increased frequency if positive or exposed to TB positive elephant	Yearly trunk wash + Stat-Pe followup if positive
Classification of animals	General:	General:
	A: Negative trunk wash culture, no exposure to TB positive elephant: no treatment or travel restrictions	1: Trunk wash culture negative, no exposure to TB positive, testing restrictions
	B: Negative trunk wash culture, exposure to TB positive elephant in last 5 years: increased testing, no travel restrictions	2: Trunk wash culture negative, exposure to TB positive elephant in 6-12 months: increase testing frequency
	C: Negative trunk wash culture, exposure to TB positive elephant in last year: Increased testing, travel restrictions, option for prophylactic treatment	3: Trunk wash culture negative, increased frequency of testing, treatment option provided based on risk
	D: Positive trunk wash culture: Treatment	4: Culture positive elephant: Treatment

	options, travel restrictions, increased testing	restrictions, increased testing quarantine without treatment
	E:Untested: no travel or contact with public or other elephants	5.: No significant change
Treatment/testing	Based on a 3 drug regimen to start, changing to 2 drugs at prescribed time Yearly trunk wash culture with increased frequency for exposure to TB positive or positive culture.	No significant changes in treatment added information and record keeping Yearly testing with trunk wash Stat-Pak, increased frequency Stat-Pak or exposure
Travel restrictions	Travel restricted if exposure to TB positive within last 12 months Travel restricted if culture positive or untested	No travel restriction if exposure last 12 months if Stat-Pak is discussion with attending veterinarian needed for this category) If Stat-Pak positive but culture restrictions but increased testing with attending veterinarians category) Travel restricted if culture positive
Further testing of Positive animals	Culture positive elephants are tested more frequently during treatment, 6 months after completion of treatment, elephants revert to 3 cultures/year	Culture positive elephants are tested frequently during treatment, treatment is completed, elephants 6 months for life with both Stat-Pak

Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
02/10/2009 10:22 AM

To Barbara A Kohn/MD/APHIS/USDA
cc

Subject Re: Blockbuster hit - Elephant document!

Here's a very rough first hack at the differences. Not a lot of detail included but I think we just need a summary. I didn't do any cleaning up because I didn't know what kind of format you were looking for.

[attachment "guideline differences.doc" deleted by Barbara A Kohn/MD/APHIS/USDA]

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Barbara A
Kohn/MD/APHIS/USDA
02/10/2009 01:21 PM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: Blockbuster hit - Elephant document!

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Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
02/10/2009 01:09 PM

To Barbara A Kohn/MD/APHIS/USDA
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Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care
Barbara A Kohn/MD/APHIS/USDA



Barbara A
Kohn/MD/APHIS/USDA
02/10/2009 08:48 AM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc
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Barb

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	B: Negative trunk wash culture, exposure to TB positive elephant in last 5 years: increased testing, no travel restrictions	2: Trunk wash culture negative, exposure to TB positive elephant in last 12 months: increase testing frequency
	C: Negative trunk wash culture, exposure to TB positive elephant in last year: Increased testing, travel restrictions, option for prophylactic treatment	3: Trunk wash culture negative, exposure to TB positive elephant in last 12 months: increased frequency of testing, travel restrictions, treatment option provided by attending veterinarian
	D: Positive trunk wash culture: Treatment options, travel restrictions, increased testing	4: Culture positive elephant: treatment options, travel restrictions, increased testing, quarantine without treatment
	E: Untested: no travel or contact with public or other elephants	5.: No significant change
Treatment/testing	Based on a 3 drug regimen to start, changing to 2 drugs at prescribed time Yearly trunk wash culture with increased frequency for exposure to TB positive or positive culture.	No significant changes in treatment added information and record keeping Yearly testing with trunk wash + Stat-Pak, increased frequency of testing with Stat-Pak or exposure
Travel restrictions	Travel restricted if exposure to TB positive within last 12 months Travel restricted if culture positive or untested	No travel restriction if exposure to TB positive within last 12 months if Stat-Pak is negative (discussion with attending veterinarian needed for this category) If Stat-Pak positive but culture negative, travel restrictions but increased testing with attending veterinarians (category) Travel restricted if culture positive
Further testing of Positive	Culture positive elephants are tested more	Culture positive elephants are tested more

animals	frequently during treatment, 6 months after completion of treatment, elephants revert to 3 cultures/year	frequently during treatment, treatment is completed, elephants 6 months for life with both Stat-Pak
---------	--	---

Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
02/10/2009 10:22 AM

To Barbara A Kohn/MD/APHIS/USDA
cc

Subject Re: Blockbuster hit - Elephant document!

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[attachment "guideline differences.doc" deleted by Barbara A Kohn/MD/APHIS/USDA]

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Barbara A
Kohn/MD/APHIS/USDA
02/10/2009 10:48 AM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
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Will be in touch.

Barb

Topic	Old Guidelines	New Guidelines
Definitions		
References		
Testing Requirements		
Classification of animals	General:	General:
	1	1
	2	2
	3	3
	4	4
	5	
Treatment/testing		
Travel restrictions		
Further testing of Positive animals		

Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
02/10/2009 10:22 AM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject Re: Blockbuster hit - Elephant document!

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[attachment "guideline differences.doc" deleted by Barbara A Kohn/MD/APHIS/USDA]

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Barbara A
Kohn/MD/APHIS/USDA
02/04/2009 03:50 PM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Elephant TB - what else?

Denise -

I have continued to work on the master document (or is that MONSTER document), so here is the latest. Please edit as you see fit. It still does not have everything, but there is more info. Let me know if I am not going in the right direction. I want to work on the draft letters tomorrow. If we can get this put together, I am hoping to be able to present it to the ACMT Feb 18 or 19.

I guess the Ringling case started today or yesterday....we are trying hard not to be drawn into it!

Andy and I are meeting with some San Diego Zoo elephant folks on Friday. AZA says there are any major concerns - the boys are out here to talk with CA senators so will be in the neighborhood. Thought I would just ask you if you are aware of anything we may be blind-sided with. SD apparently has a new elephant exhibit....have you seen it?

Have a great day!

Barb



Elephant TB testing Document all.doc



Barbara A
Kohn/MD/APHIS/USDA
01/28/2009 12:03 PM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: elephant issues

Great - I should have a better outline of what to get together tomorrow. While I am working at home today (until 4PM), the boys are home too, so I don't get quite as much done as I normally would. Tomorrow I am at home as well, but the kids should be back in school! Yeah!!!

Keep it to e-mail till your throat is healed...I will be in touch tomorrow.

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
01/28/2009 11:49 AM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject Re: elephant issues

That's good. I never seem to remember when these meetings are. Hard enough to keep track of myself. ;-)

I'm feeling a bit better. Had a nasty sore throat and cold and didn't want to talk and make it worse. So, I did a bit of e-mail monitoring and as little talking as possible.

I like the idea of a whole package approach. Let me know what I can do to help with that.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care
Barbara A Kohn/MD/APHIS/USDA



Barbara A
Kohn/MD/APHIS/USDA
01/28/2009 08:29 AM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc
Subject Re: elephant issues

Denise -

Hope you are feeling better! Yesterday we all had communications training (amidst a snow storm) and today most of us are working at home because we are iced out! Guess it is OK as it is the first real "storm" of the season. By noon the temps are suppose to be above freezing and we should get just rain.....So, I haven't gotten much done yet. The ACMT meeting is the third week in February (I have no idea when or why it was changed, but Jodie thought it was next week, and Bob corrected her. So, I think we have time

to get a package together. I talked briefly yesterday before training with Betty and Bob - asked if you had been in touch yet, but provided a real general summary of what we are doing, so they know they will hear from you soon. I assured them that the documents and plans will be run by them first!

It will be work, but I would love to be able to put together a whole book/presentation, that has draft letters and protocols, a timeline, the export letter, and all - all laid out with the hopes that they will be few, if any, changes....Does that seem OK with you?

Thanks.

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
01/28/2009 10:17 AM

To Barbara A Kohn/MD/APHIS/USDA
cc

Subject elephant issues

Hey Barb,

I've been out sick the first two days of this week and am back and getting caught up.

I think there is an ACMT meeting this week. Do you know if Tracy was going to raise the issue of the Stat-Pak and new guidelines?

I was not able to reach anyone in the regions before this week to run it by them. Bob and Betty were aware of the proposals from last summer but I really wanted to update them.

Hope that didn't cause any issues.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Barbara A
Kohn/MD/APHIS/USDA
01/28/2009 10:29 AM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: elephant issues

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Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
01/28/2009 10:17 AM

To Barbara A Kohn/MD/APHIS/USDA
cc
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Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Barbara A
Kohn/MD/APHIS/USDA
01/23/2009 10:06 AM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc

Subject Re: Reporting table - draft What do you think?

I am OK with that - was thinking if the test, for whatever reason was equivocal - may recommend retesting. It could easily be put into a comments block and not imply that the Fed Vet is issuing recommendations. You are correct, those should come from the regional office.... That is why it is a Draft!! :>)

Tracy is back in the office today, but I haven't spoken with her yet, so still plenty of time to get the caffeine!

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
01/23/2009 10:02 AM

To Barbara A Kohn/MD/APHIS/USDA
cc

Subject Re: Reporting table - draft What do you think?

I like the table but would probably delete the recommendations section. I think comments are fine if restricted to the actual running of the test but I think recommendations should come from another source. If you're thinking of further testing recommendations, I think those are clearly outlined in the guidelines.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Barbara A
Kohn/MD/APHIS/USDA
01/23/2009 09:22 AM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Draft protocol

Denise -

Here is the first attempt. Need your read on content and if more or less detail is needed. Would like to work on a basic form that can be used.....

Thanks.

Happy Friday!

Barb

Tests ordered from Chem-Bio or NVSL

Both providers will supply Animal Care with a list of purchasers and number of tests, as well as ID test # or lot #

Guidelines require at least yearly testing of elephants using Stat-Pak. Official test will be done under the direct supervision of Federal Veterinarian – Animal Care or AC designated Federal Veterinarian.

MOU's with State veterinarians will be explored after 2nd year of implementation.

Animal Care will coordinate testing date with licensee. VMO, SACS, and/or Field Specialist will be the Federal Veterinarian designated to perform the Stat-Pak tests.

Federal Vet responsibilities:

- Positive identification of all animals being tested (including pictures).
- Identification of all elephants on premise not tested that day
- Identification of all animals traveling that day.
- Direct observation of blood draws
- Perform the Stat-Pak test for each elephant tested that day.
- Record results, providing copy for licensee and copy for AC (facility file)
- Year one – review established trunk wash routine
- Year two – observe trunk washes for animals tested that day; review sample handling and submission protocols with licensee.

If the licensee prefers, the Federal Veterinarian will verify animal identities and monitor the collecting of blood samples. Under Federal Vet supervision, the blood samples will be packed and shipped to NVSL for testing.

Prior to testing oversight, all involved AC veterinarians will receive training in the Stat-Pak test, including sample collection, sample handling, carrying out the test, sample packaging and shipping to NVSL, and recordkeeping for the test.



Barbara A
Kohn/MD/APHIS/USDA
01/21/2009 12:34 PM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: guidelines 

USAHA did not send a copy with the letter they sent to Chester. I do have a copy that is dated October 29, 2008, which I think is the approved version. Here it is....it was originally sent as a Draft, but dated for final approval.

Barb



DRAFT no distribute TB Guidelines Oct 29, 2008 final.doc
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
01/21/2009 11:17 AM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject guidelines 

Just checking to make sure we have the final, final version of the guidelines. I have a version that is dated March 2007. Seems odd but I think that may be the final. Just to be on the safe side though, did USAHA send a copy of the guidelines they approved along with the resolution? If not, I'll get a copy from Michele or Kathy to make sure we have the right version.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Barbara A
Kohn/MD/APHIS/USDA
01/13/2009 01:17 PM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Elephant/TB Issues

Denise - It was sent yesterday (Jan 12) Here is the forwarded message. should have all the info.

Thanks.

Barb

----- Forwarded by Barbara A Kohn/MD/APHIS/USDA on 01/13/2009 01:18 PM -----

Calendar Entry
Meeting



Subject	Elephant/TB Issues
---------	--------------------

Chair	Tracy L Bowman/MD/APHIS/USDA
-------	------------------------------

When	Starts	Fri 01/16/2009	03:00 PM	1 hour
	Ends	Fri 01/16/2009	04:00 PM	

Location	2B09
Where	Reserved No rooms or resources have been reserved

Invitees	Invited	The following invitees have been invited
	Required (to)	Barbara A Kohn/MD/APHIS/USDA@USDA, Charles W Hench/CO/APHIS/USDA@USDA, David R Kinker/IA/APHIS/USDA@USDA, Denise M Sofranko/NM/APHIS/USDA@USDA, Francisco Collazo-Mattei/MD/APHIS/USDA@USDA, Joyce W Bowling-Heyward/MD/APHIS/USDA@US DA, Kathy A Orloski/CO/APHIS/USDA@USDA, Larry R Ludemann/IA/APHIS/USDA@USDA, LeeAnn Thomas/MD/APHIS/USDA@USDA, Paul J Hauer/IA/APHIS/USDA@USDA, Ray.R.Waters@usda.gov, rwaters@nadc.ars.usda.gov, Thomas O Bunn/IA/APHIS/USDA@USDA

Categorize	
------------	--

Description

Denise and Barb will be sending you some summary information to catch everyone up on the issues - stay tuned!

The call in number is: 87-937-5622 429788#

Do not send government line

Your Notes



Barbara A
Kohn/MD/APHIS/USDA
01/13/2009 12:47 PM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: TB issues conference call documents

I have no problem with that. Maybe you can send Tracy and e-mail (she is in KC for the Fed-State meeting). If she is OK with it we can invite and send the info to them Tracy was a little stressed yesterday before she left. In fact, we spent about a half hour past my regular leaving time discussing FOIA stuff - I think we have fried her mind these past few weeks..... I know you mentioned the names to her before, but I don't think she has thought about adding them....

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
01/13/2009 12:43 PM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject Re: TB issues conference call documents

How about adding Beth Harris and Jeff Nelson from the lab? Jeff runs the stat-pak and can describe that process and Beth is the head of the Mycobact. section.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Barbara A
Kohn/MD/APHIS/USDA
01/09/2009 02:59 PM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject AC VS meeting on Stat Pak - DRAFT summary page to keep all on track.

Denise - if you have a moment - can look over the first draft of the 1 page summary Tracy wanted for next Friday's meeting? Please correct any errors I made. It all sounds logical when we talk, then I try to write it down.....

Barb

Elephant Tuberculosis Surveillance and Treatment Amended Protocols under the AWA

ISSUE

Animal Care (AC) is committed to moving forward with improved guidance and testing for elephant tuberculosis (TB) based on science and expert knowledge. USAHA has recommended that AC accept and use the updated "Guidelines for the Control of Tuberculosis in Elephants 2008" to continue our current monitoring and treatment requirements under the Animal Welfare Act (AWA). These new guidelines incorporate the use of Chem-Bio's Elephant Stat-Pak in conjunction with the more traditional trunk wash with culture and sensitivity. The licensing restrictions for this new test requires innovative thinking to allow for ease of use and preventing fraudulent results.

BACKGROUND

AC has been requiring TB testing and treatment of elephants since 1998, with amendments to guidelines in 2000 and 2003.

The working group that developed the original guidance has been replaced with a subcommittee of USAHA.

USAHA has accepted the 2008 guidelines and requested that APHIS accept them.

The 2008 document utilizes a recently (August 2007) licensed new diagnostic screening test from Chem-Bio (Elephant Stat-Pak).

Licensing restriction on this product makes NVSL the only current US lab that is authorized to run the test.

Some AWA licensed entities have sent samples overseas for testing rather than have USDA run the test. Without proper Endangered Species Act permits, this is illegal. US Fish and Wildlife Service has already fined one veterinarian.

AC needs to find a way to allow use of the test in the field without encouraging fraudulent results.

USDA personnel (AC, VS, NVSL, ARS) have held a discussion about the test and issues and developed a proposed solution for distribution and use of the Elephant Stat-Pak.

State, Federal, accredited and attending veterinarians would be allowed to buy the tests from Chem-Bio, but the official testing of elephants must be done by State or Federal veterinarians. Chem-Bio would supply APHIS with a list of buyers.

ACTIONS NEEDED

1. Verification from VS NCIE that they have no restrictions on the export of endangered species blood samples for testing.

(AC can then distribute letter to licensees and registrants advising them of ESA restrictions)

2. Concurrence of VS and NVSL that AC, in support of the new elephant TB monitoring and treatment guidelines, can designate attending veterinarians as “labs” with respect to the licensing parameters of the elephant TB Stat-Pak (Chem-Bio), requiring that any official test done under the new guidelines is done by State or Federal veterinarians to control fraudulent use of the tests.

(AC can formalize protocol for designating “lab” and develop a letter to elephant holders explaining the process and protocols, including the parameters of an official test)

(AC can then inform USAHA that we will accept the revised version of the guidelines for elephant TB monitoring and testing, as send the new guidelines to our elephant holders, informing them of the implementation date, and placing the information and new guidelines on the AC web site.)



Barbara A
Kohn/MD/APHIS/USDA
01/05/2009 02:58 PM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: Elephant briefing January 8 and recommendations on meeting with VS regarding TB

Thanks, Denise...And thanks for adding the names....Didn't know exactly who was who...Love to have the heads of departments and programs....

Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
01/05/2009 02:56 PM

To Barbara A Kohn/MD/APHIS/USDA
cc Andrea M Morgan/MD/APHIS/USDA@USDA, Tracy L Bowman/MD/APHIS/USDA@USDA
Subject Re: Elephant briefing January 8 and recommendations on meeting with VS regarding TB

I suggest including someone from the TB section at NVSL. Beth Harris, Head of the Mycobacterian and Brucellosis Section is familiar with the issues and testing as is Janet Payeur, Scientific Outreach at NVSL. SueLee Robbe-Austerman is the head of the TB testing lab at NVSL.

You were close on the spelling for Kathy: Kathy Orloski. ;-)

Looking forward to the meeting.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care
Barbara A Kohn/MD/APHIS/USDA



Barbara A
Kohn/MD/APHIS/USDA
01/05/2009 12:43 PM

To Tracy L Bowman/MD/APHIS/USDA@USDA, Andrea M Morgan/MD/APHIS/USDA@USDA
cc Denise M Sofranko/NM/APHIS/USDA@USDA
Subject Elephant briefing January 8 and recommendations on meeting with VS regarding TB

Tracy and Andy -

Denise can come to Riverdale on Thursday, January 8, 2009. Although we can use less time, I have reserved a meeting room (Room 3A02, the Calvert Room) from 10 AM - 4 PM. We can fit the briefing around preferred break times. Denise is working on a draft agenda (listing of the various animals and issues) so we can keep on track - yes, Denise and I can discuss elephants for days!

I would strongly recommend that the AC conference call/meeting with our VS counterparts be scheduled after this briefing sometime (Not this Friday, as Denise is traveling home). Perhaps next Thursday or Friday? I don't think I have a final list of suggested VS participants, but a number of VS persons have been involved in discussions and development of draft documents on the topic of elephant TB testing in

the past. Again, I would recommend (strongly) that the following persons be included in the proposed discussions for continuity and background information:

Dr. Bill Hench (TB Staff in Fort Collins)
Dr. Tom Bunn (NVSL)
Dr. LeeAnn Thomas (VS)
Dr. Ray Waters (NVSL)
Dr. Cathy Orlofsky (my spelling is likely wrong)
Dr. Denise Sofranko (AC)

I will be providing a summary of the issues and outline the actions to be taken today or tomorrow morning.

Thanks.

Barb



Barbara A
Kohn/MD/APHIS/USDA
12/17/2008 03:06 PM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: letter from USAHA

Tracy is still here as the acting Assistant Deputy Administrator, and Andy is the Associate Deputy Administrator. I think this still leaves Tracy with the supervision of the staff officers. Prior to EM duties (Allan), the Associate DA was more the direct supervisor and liaison with the Regional Directors....Who know what Chester has in mind. I am afraid Andy will be here pretty much on her own for the next 2 weeks, as most of us have leave for the holidays!

Oh, well....The new year should be interesting....

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
12/17/2008 03:01 PM

To Barbara A Kohn/MD/APHIS/USDA@USDA
cc
Subject Re: letter from USAHA

I'll send the guidelines when I get a chance.
We can maybe get a running start first of the year.

Did hear about andy. Maybe it's an effort for her to diversify? I was going to give her a call and check in.
Where does this leave tracy?
Barbara A Kohn

----- Original Message -----

From: Barbara A Kohn
Sent: 12/17/2008 02:08 PM EST
To: Denise Sofranko
Subject: Fw: letter from USAHA

Denise -

While, technically, USAHA did send this before Monday, as you can see by the date, they didn't send the letter until last week. Toni received it today (or maybe yesterday afternoon) and sent it electronically to Chester today. Chester is on leave - I think until the end of the year. I hope this means we can move forward more rapidly in January. Guess we will have to supply the copy of the guidelines - they were not included with the letter....

So, has it been made known in the outer realms that Andi Morgan is becoming an AC Associate Deputy Administrator on Monday? This was a big surprise to all of us - didn't know we were looking for one. Allan is still with us, but no one is sure if he retains his title or just his position as emergency management director.....always something fun!

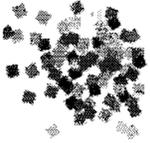
Barb

----- Forwarded by Barbara A Kohn/MD/APHIS/USDA on 12/17/2008 02:03 PM -----



Tondalee
Smith/MD/APHIS/USDA

To Barbara A Kohn/MD/APHIS/USDA@USDA



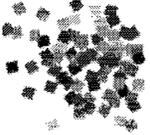
12/17/2008 01:55 PM

cc

Subject Fw: letter from USAHA

Toni Smith
USDA-APHIS
Animal Care
301-734-4980

----- Forwarded by Tondalee Smith/MD/APHIS/USDA on 12/17/2008 01:56 PM -----



Tondalee
Smith/MD/APHIS/USDA
12/15/2008 02:15 PM

To Chester A Gipson/MD/APHIS/USDA

cc

Subject letter from USAHA

[attachment "USAHA RESOLUTION 40, 49.pdf" deleted by Denise M Sofranko/NM/APHIS/USDA]

Toni Smith
USDA-APHIS
Animal Care
301-734-4980



Barbara A
Kohn/MD/APHIS/USDA
12/17/2008 02:08 PM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc

Subject Fw: letter from USAHA

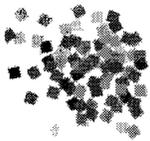
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Barb

----- Forwarded by Barbara A Kohn/MD/APHIS/USDA on 12/17/2008 02:03 PM -----



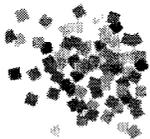
Tondalee
Smith/MD/APHIS/USDA
12/17/2008 01:55 PM

To Barbara A Kohn/MD/APHIS/USDA@USDA
cc

Subject Fw: letter from USAHA

Toni Smith
USDA-APHIS
Animal Care
301-734-4980

----- Forwarded by Tondalee Smith/MD/APHIS/USDA on 12/17/2008 01:56 PM -----



Tondalee
Smith/MD/APHIS/USDA
12/15/2008 02:15 PM

To Chester A Gipson/MD/APHIS/USDA
cc

Subject letter from USAHA



USAHA RESOLUTION 40_49.pdf

Toni Smith
USDA-APHIS
Animal Care
301-734-4980



Barbara A
Kohn/MD/APHIS/USDA
12/16/2008 12:15 PM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: Fw: Elephant TB Guidelines

Lovely - how to tactfully tell him to look on his desk!

I will talk with Toni (his secretary) tomorrow when I am in and maybe we can hunt it down.... If not, who should we approach to resend it..

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
12/16/2008 12:05 PM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject Fw: Elephant TB Guidelines

fyi

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

----- Forwarded by Denise M Sofranko/NM/APHIS/USDA on 12/16/2008 10:06 AM -----



(b)(6)
msn.co
m>
12/16/2008 09:52 AM

To "Denise Sofranko USDA Animal Care"
<Denise.M.Sofranko@aphis.usda.gov>
cc
Subject Fw: Elephant TB Guidelines

See (b)(6) reply.

Resolution 49 must be sitting on Chester's desk amid all the Christmas wrapping paper, ribbon and cards.

(b)(6)

Foxglove Consulting
522 Flora Vista Road NE
Olympia, WA 98506
home/office (b)(6)
e-mail (b)(6) msn.com

----- Original Message -----
From (b)(6)

To: (b)(6)
Sent: Monday, December 15, 2008 12:16 PM
Subject: RE: Elephant TB Guidelines

Hi (b)(6)
The resolution was sent to Chester Gipson as head of USDA-APHIS-AC. Let me know if we need to send to any others.

FYI on our process, we try to send the resolutions to the head individual of whichever agency/department/division is named in the resolution.

Let me know if you need anything else,
(b)(6)

From: (b)(6) [redacted]@msn.com]
Sent: Monday, December 15, 2008 2:03 PM
To: (b)(6)
Subject: Fw: Elephant TB Guidelines

Dr. Sofranko had a question about Resolution 49. Who was that resolution addressed to?

Thanks.

(b)(6) [redacted]

Foxglove Consulting
522 Flora Vista Road NE
Olympia, WA 98506
home/office (b)(6)
e-mail (b)(6)@msn.com

----- Original Message -----
From: Denise.M.Sofranko@aphis.usda.gov
To: (b)(6)
Sent: Monday, December 15, 2008 11:50 AM
Subject: Elephant TB Guidelines

Hi (b)(6)

Just checking to make sure I'm not missing something on our end.

When the resolution for the new Guidelines was sent to USDA, who did it go to? I'm not familiar with the process.

Hope all goes well with you.

thanks!

Denise M. Sofranko, DVM
Field Specialist for Elephants



Barbara A
Kohn/MD/APHIS/USDA
12/16/2008 09:59 AM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc
bcc
Subject Re: Elephant TB guidelines

Will let you know. TJ is TJ Meyers - a VS guy who is notoriously slow in responding to anyone. I contacted him in October regarding the blood export letter. In spite of Chester's intervention, still not a word. Maybe Tracy can get thru.

Barb.

Off to the dentist I go!!!

Denise M Sofranko

----- Original Message -----

From: Denise M Sofranko
Sent: 12/16/2008 07:49 AM MST
To: Barbara Kohn
Subject: Re: Elephant TB guidelines

Thanks Barb,
Let me know how I can help.
Who is T.J.?

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care
Barbara A Kohn/MD/APHIS/USDA



Barbara A
Kohn/MD/APHIS/USDA
12/16/2008 06:19 AM

To Chester A Gipson/MD/APHIS/USDA@USDA
cc Denise M Sofranko/NM/APHIS/USDA@USDA, Tracy L
Bowman/MD/APHIS/USDA@USDA
Subject Re: Elephant TB guidelines

Thanks, Chester. Will do tomorrow when I am in Riverdale.

Barb
Chester A Gipson/MD/APHIS/USDA

Chester A
Gipson/MD/APHIS/USDA
12/16/2008 08:04 AM

To Barbara A Kohn/MD/APHIS/USDA@USDA
cc Denise M Sofranko/NM/APHIS/USDA@USDA tracey
bowman
Subject Re: Elephant TB guidelines

Barb,

I am awaiting a response from TJ on the issue. Brief Tracey on the issue so she can follow-up with TJ. Interestingly I have not received a copy of the resolution for response from the TB committee and did receive one from the Equine committee. I will also give TJ a call.

Thanks,

C. Gipson

301 734 4980

Barbara A Kohn/MD/APHIS/USDA



Barbara A

Kohn/MD/APHIS/USDA

12/15/2008 03:14 PM

To Chester A Gipson/MD/APHIS/USDA@USDA

cc Denise M Sofranko/NM/APHIS/USDA@USDA

Subject Elephant TB guidelines

Chester -

Just one more thing to deal with before the holidays...sorry.

People are starting to ask AC questions about the approved new TB guidelines for elephants and we are wondering if anything official (regarding the USAHA resolution) has come down through the Agency. Denise and I are eager to get the information distributed and deal with the StatPak testing issues. APHIS needs to observe and monitor the official tests using the StatPak to insure against mistakes.

Would love to hear that AC and VS are on the same page. We can draft all of the documents needed to roll out the new guidelines as soon as APHIS agrees to the USAHA resolution....

I am out for 2 weeks starting next Monday and would love to have most, if not all, done this week before I go....

Thanks for you help and cooperation.

Barb



Barbara A
Kohn/MD/APHIS/USDA
09/03/2008 01:13 PM

To Denise M Sofranko/NM/APHIS/USDA, Michael Carpenter
cc
bcc

Subject 2nd draft elephant TB testing letter from APHIS

Denise and Mike -

First, apologies to Mike for totally missing his earlier response (feel free to concoct your own excuse! :>))

Attached is the revised letter with FWS corrected info. Hope I got it right, now. If everyone is OK with this, Denise, I think we need to send it to Chester and the management team for prompt review. Mike, does FWS want to sign it, or are you OK with it going out just under our signature?

Thanks to all for your input and help..... I promise to note comments promptly this time around!

Barb



Draft elephant TB testing export letter.doc



United States
Department of
Agriculture

Animal and Plant
Health Inspection
Service

4700 River Road
Riverdale, MD
20737

Dear Elephant Holder:

It has been brought to our attention that some parties are shipping blood samples being tested for tuberculosis out of the United States for analysis using the Chem-Bio Rapid Stat-Pak elephant tuberculosis test kit. While use of a foreign lab is not, in and of itself, illegal, there are legal requirements that must be met before any export of samples from endangered species can take place. Any movement of blood or bodily fluids/parts from an endangered species, such as the Asian or African elephant, must be accompanied by valid Endangered Species Act (ESA) and CITES permits. These permits are issued by the US Fish and Wildlife Service through their Division of Management Authority. The permitting process does take time. During the process, APHIS is generally contacted to provide input and recommendations on the permits. In addition, there is a mandatory public comment period for the ESA permit. Information and application forms can be found on the Fish and Wildlife Service web site at <http://www.fws.gov>. The CITES/ESA application form for biological samples can be found at <http://www.fws.gov/forms/3-200-29.pdf>.

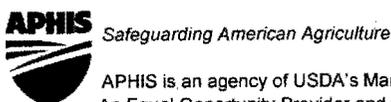
The need for a CITES import permit (from the country receiving the samples, and/or a CITES export permit, is determined based on the material/species and the circumstances. Guidance on these parameters can be found on the Fish and Wildlife Service web site at <http://www.fws.gov> or http://www.fws.gov/le/pdf/CITES_Document_Requirements-11-14-2007.pdf

As you may be aware, violation of Federal laws may involve a fine and/or jail time.

It should be noted that the elephant tuberculosis kit, Chem-Bio Stat-Pak®, is available in the USA through the National Veterinary Services Laboratory in Ames, Iowa. Blood samples can be sent to this laboratory for analysis. The current (2003) tuberculosis testing and monitoring guidelines referenced in APHIS, Animal Care's Policy #21, do not require the Chem-Bio test, but a number of States are requiring a related test, the MAPIA test, for the transport of any elephant into or through their state. Once implemented, the amended guidelines (2008) will require the Stat-Pak® test for all elephants regulated under the AWA.

Sincerely,

Chester A. Gipson
Deputy Administrator
Animal Care



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Federal Relay Service
(Voice/TTY/ASCII/Spanish)
1-800-877-8339



Barbara A
Kohn/MD/APHIS/USDA
08/07/2008 08:31 AM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: Stat-Pak out of country 

Denise -

Sorry I couldn't get back to you yesterday. I have been out on leave and am now trying to catch up. I don't have the letter written yet, but it is on my list. I will send a draft to you and Mike Carpenter (FWS), and then we begin the approval process....I hope to have something ready by Monday. Have a couple of projects that need to be done before then, neither of which I really want to do, so it is taking a while! Safe travels today.

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
08/06/2008 02:23 PM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject Stat-Pak out of country

Hey Barb,
I'm catching up on things this week. Where are we with the issue of people sending blood out of country for Stat-Pak testing? Is FWS going to pursue it? Do we need to put a letter together or has that been decided?
I'm in my office today so you can call if you want to discuss. Traveling tomorrow.
thanks!
d

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Barbara A
Kohn/MD/APHIS/USDA
07/10/2008 07:39 AM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: TB testing - StatPak

Denise -

I know you already provided some info about the foreign tests. Could you send me all the details and I will talk to FWS about what they can and cannot do with the info? I don't see a problem with supplying the info....they can make the decision whether or not to investigate....

About the rest...I am feeling frustrated and impatient, but not surprised...Wish we could find the right buttons to push to address the use issue effectively....

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
07/09/2008 04:06 PM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject Re: TB testing - StatPak

Thanks Barb,
I was just wondering about that this morning and figured nothing was going to happen. We'll still have to deal with the issue after USAHA. I'm guessing John has already seen it because I'm assuming LeeAnn Thomas sent it to him. Probably the folks from NVSL did as well.

I think the letter would be good. Wish FWS would check into the ones that have already done this and send them at least a "stern" letter.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care
Barbara A Kohn/MD/APHIS/USDA



Barbara A
Kohn/MD/APHIS/USDA
07/09/2008 11:43 AM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc
Subject TB testing - StatPak

Denise -

I talked with Chester today (about multiple things) and he brought up the document we have submitted to him regarding the test. He has not shown Dr. Clifford the document yet, but has, he said, started to talk to

him about it. He indicated that APHIS would do something before the USAHA meeting.... Not the response I really wanted, but I hope to be able to prod this along. Maybe I can draft a letter soon regarding the legalities of shipping samples out of the country.....as a separate item, recommending that we distribute to our elephant holders.....

Barb



Barbara A
Kohn/MD/APHIS/USDA
07/09/2008 01:43 PM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject TB testing - StatPak

Denise -

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Barb



Barbara A
Kohn/MD/APHIS/USDA
06/12/2008 03:25 PM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: some preliminary answers

That sounds fine. Just sub our section for his in the document. I am sure they will be some further discussion, so exact format is not an issue right now.

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
06/12/2008 03:20 PM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject Re: some preliminary answers

How about if I just reply to his e-mail and send this copy back with a note that comments are in blue? Should we do any other sort of format or formalizing to it? I sort of see it as a discussion anyway.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care
Barbara A Kohn/MD/APHIS/USDA



Barbara A
Kohn/MD/APHIS/USDA
06/12/2008 01:17 PM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc
Subject Re: some preliminary answers

I am OK with the document. I say we go for it. Yes to sending to Chester and cc'ing Betty and Bob. Let's move forward so we can start using the test. Hopefully USAHA will accept the protocols in the surveillance and monitoring guidelines and we can really start using MAPIA

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
06/12/2008 03:13 PM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject Re: some preliminary answers

I'm good to go with this if you are. Can we just send it to Chester with a note that you and I have answered his questions and cc Bob and Betty? It would be nice to get it back to him as soon as we can.

thanks!

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care
Barbara A Kohn/MD/APHIS/USDA



Barbara A
Kohn/MD/APHIS/USDA
06/12/2008 01:08 PM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc
Subject Re: some preliminary answers

Denise -

I think your draft captured the essence of what we need to say. I did edit some of the sentences. Please see what you think. I also crossed out the red in the first bullet and added a note in green. I wanted to cross out all the red, but left the other actual comments untouched (great restraint on my part! :->)

Unless we are missing something obvious, I think we have made the case to retain the wording and intent of the original document....

Barb

[attachment "stat-pakquestions.doc" deleted by Barbara A Kohn/MD/APHIS/USDA]
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
06/12/2008 02:11 PM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject some preliminary answers

My comments in blue

[attachment "stat-pakquestions.doc" deleted by Barbara A Kohn/MD/APHIS/USDA]

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Barbara A
Kohn/MD/APHIS/USDA
06/12/2008 03:17 PM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: some preliminary answers

I am OK with the document. I say we go for it. Yes to sending to Chester and cc'ing Betty and Bob. Let's move forward so we can start using the test. Hopefully USAHA will accept the protocols in the surveillance and monitoring guidelines and we can really start using MAPIA

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
06/12/2008 03:13 PM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject Re: some preliminary answers

I'm good to go with this if you are. Can we just send it to Chester with a note that you and I have answered his questions and cc Bob and Betty? It would be nice to get it back to him as soon as we can. thanks!

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care
Barbara A Kohn/MD/APHIS/USDA



Barbara A
Kohn/MD/APHIS/USDA
06/12/2008 01:08 PM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc
Subject Re: some preliminary answers

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[attachment "stat-pakquestions.doc" deleted by Barbara A Kohn/MD/APHIS/USDA]
Denise M Sofranko/NM/APHIS/USDA



Denise M



Sofranko/NM/APHIS/USDA

06/12/2008 02:11 PM

To Barbara A Kohn/MD/APHIS/USDA

cc

Subject some preliminary answers

My comments in blue

[attachment "stat-pakquestions.doc" deleted by Barbara A Kohn/MD/APHIS/USDA]

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Barbara A
Kohn/MD/APHIS/USDA
06/12/2008 03:08 PM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: some preliminary answers 

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Barb



stat-pakquestions.doc

Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
06/12/2008 02:11 PM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject some preliminary answers

My comments in blue

[attachment "stat-pakquestions.doc" deleted by Barbara A Kohn/MD/APHIS/USDA]

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Barbara A
Kohn/MD/APHIS/USDA
05/01/2008 07:08 AM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc
bcc
Subject Re: Stat-Pak

Go for it! Let's see what happens.

Barb

----- Original Message -----

From: Denise M Sofranko

Sent: 04/30/2008 04:25 PM MDT

To: Barbara Kohn; Charles Hench; Jeffrey Nelson; Kathy Orloski; Larry Ludemann; LeeAnn Thomas; Ray Waters
<ray.waters@ars.usda.gov>; Denise Sofranko; Thomas Bunn; Paul Hauer; Janet Payeur

Subject: Stat-Pak

Hi all,

I've had a conversation with LeeAnn Thomas about a few more edits to this doc. The changes made were regarding Veterinary Services. While we anticipate that if we need VS personnel in the future to assist in supervising field testing, at this time it would be less complicated to not have that specifically in the document. So we've changed the supervision to State Veterinary personnel or AC veterinarians.

I am planning on sending this forward to both AC Regions with the expectation that they will send it on to the Deputy Administrator for AC. I will send a short explanation of the document that will include a list of participants at the meeting (or on the phone) and that we have concurrence with the document. Please let me know if you do not want me to include you on this list.

Unless any of you anticipate that there will be any actions needed on the part of your groups, you might want to send it forward as an fyi. I will cc you all on the e-mail I send forward to AC. If any of you want to just forward that as part of your FYI, feel free to do so.

Thanks again for all of your help and patience on this. Hopefully this really is the final doc.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Barbara A
Kohn/MD/APHIS/USDA
04/21/2008 10:10 AM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: Fw: Zerbini elephants and public exposure 

Denise -

I like the approach Tom outlined....makes it seem more official and not us picking on anyone. I will respond shortly to Tom's e-mail and recommend the course of action and that the ERO draft the report (not sure how that will go over, but it is their bailiwick). What do you think?

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
04/21/2008 09:51 AM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject Fw: Zerbini elephants and public exposure

What do you think of this? Should we put some sort of situation report together?

Let me know how I can help.
thanks

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

----- Forwarded by Denise M Sofranko/NM/APHIS/USDA on 04/21/2008 07:50 AM -----



"Gomez, Thomas M.
(CDC/CCID/NCZVED)"
<tmg1@cdc.gov>
04/18/2008 01:10 PM

To Denise.M.Sofranko@aphis.usda.gov,
Barbara.A.Kohn@aphis.usda.gov
cc Ray.M.Flynn@aphis.usda.gov,
Gregory.S.Gaj@aphis.usda.gov, "Gomez, Thomas M.
(CDC/CCID/NCZVED)" <tmg1@CDC.GOV>
Subject RE: Zerbini elephants and public exposure

Thanks Denise, Barb.

Is the intent to notify both animal (CFIA) and public health (Health Canada or the Public Health Agency of Canada) -- I would say 'yes'?

My suggestion is for someone to draft a situation report on the elephant(s) of concern. This can then be sent to CFIA and discussed with CDC with a request to have CDC notify their counterparts in Canada (and coordinate with CFIA); or request CFIA to share the report with their public health counterparts for any action they deem necessary. Thoughts??

Discussion with CDC should also include any public exposure in the US.

Tom G.

-----Original Message-----

From: Denise.M.Sofranko@aphis.usda.gov
[mailto:Denise.M.Sofranko@aphis.usda.gov]
Sent: Friday, April 18, 2008 1:25 PM
To: Barbara.A.Kohn@aphis.usda.gov
Cc: Ray.M.Flynn@aphis.usda.gov; Gomez, Thomas M. (CDC/CCID/NCZVED);
Gregory.S.Gaj@aphis.usda.gov
Subject: Re: Zerbini elephants and public exposure

We've been working with FL and now with MI state vets and/or public health.

Are you talking about contact information for people or animals? I think we have a good handle on the animal end of things.

I'm ccing Greg on this as well because I should have had him on the original e-mail.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

Barbara A

Kohn/MD/APHIS/USD

A

To

Denise M

04/18/2008 11:17

Sofranko/NM/APHIS/USDA@USDA

AM

cc

Ray M Flynn/CO/APHIS/USDA@USDA,

tgomez@cdc.gov

Subject

Re: Zerbini elephants and public
exposure(Document link: Denise M
Sofranko)

Denise -

Yes, I just talked briefly to Chester about another issue and he brought this situation up. It has been suggested that perhaps State of FL can ask for our help in studying/documenting epidemiology of the case , thereby allowing us perhaps better access to contact information for all animals involved. Apparently (b)(6) recently talked with (b)(6) and we do not know what, if anything was said by them or APHIS.

I agree that we should let Canada know. I think Chester is going to be talking to Betty about this yet today....

Barb

Denise M
Sofranko/NM/APHIS
/USDA
To tgomez@cdc.gov, Barbara A
04/18/2008 12:28 Kohn/MD/APHIS/USDA
PM
cc Ray M Flynn/CO/APHIS/USDA@USDA
Subject Zerbini elephants and public
exposure

Tom and Barb,

We should probably address in some fashion the issue of the TB positive elephant and her public exposure in the last year or so. I'm attaching the itinerary from last year and you can see that they were in Canada for a large portion of it. I've spoken to Ray Flynn about this and we feel that we should let the Canadians know so they can determine if they need to do anything further. We need to let Chester know before we do that and decide who will provide the information.

We just got a communication from PETA about Luke and Roxie (on one of the Ringling units) being exposed so I think it's a matter of time before they start looking at the itineraries and such. Probably a good idea to get the information out first.

What do you guys think?

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

[attachment "2007itin.pdf" deleted by Barbara A Kohn/MD/APHIS/USDA]



2007itin.pdf



Barbara A
Kohn/MD/APHIS/USDA
04/18/2008 01:47 PM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: Fw: Concerns re: TB-exposed elephants and Ringling's blue unit

Thanks, Denise -

Chester has cc'd me this this am.....

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
04/18/2008 01:45 PM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject Fw: Concerns re: TB-exposed elephants and Ringling's blue unit

I don't see your name anywhere in the ccs so here ya go.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

----- Forwarded by Denise M Sofranko/NM/APHIS/USDA on 04/18/2008 11:44 AM -----

Chester A
Gipson/MD/APHIS/USDA
04/18/2008 08:48 AM

To (b)(6)@peta.org>
cc Betty.J.Goldentyer@aphis.usda.gov,
Robert.M.Gibbens@aphis.usda.gov, (b)(6)
(b)(6)@peta.org>, (b)(6)
Subject Re: Concerns re: TB-exposed elephants and Ringling's blue unit

To: (b)(6)

This is to acknowledge receipt of your letter and we will evaluate and respond as appropriate.

Thanks,
C. Gipson
301 734 4980

(b)(6)@peta.org>



(b)(6)
(b)(6)@peta.org>
04/18/2008 10:05 AM

To <Chester.A.Gipson@aphis.usda.gov>
cc <Betty.J.Goldentyer@aphis.usda.gov>,
<Robert.M.Gibbens@aphis.usda.gov>, (b)(6)
(b)(6)@peta.org>
Subject Concerns re: TB-exposed elephants and Ringling's blue unit



URGENT

April 18, 2008

Chester Gipson, D.V.M.
Associate Deputy Administrator
USDA-APHIS-VS
4700 River Rd., Unit 84
Riverdale, MD 20737-1232

Via e-mail

Dear Dr. Gipson:

Please consider this letter an official request for the USDA to investigate the following situation regarding Feld Entertainment, dba "Ringling Bros. and Barnum & Bailey Circus" in Vienna, Virginia, license #52-C-0137.

As an addendum to our complaint sent to Dr. Goldentyer on April 14, 2008, PETA has obtained additional information from an informed source regarding the two Zerbini elephants, believed to be Luke and Roxy, who were just pulled off Ringling's gold unit. According to the whistleblower, the elephants were pulled off the unit because they were exposed to TB through their contact with Jan, a recently deceased, TB-positive elephant. The source tells PETA that Luke and Roxy—now considered Group C elephants—were allegedly in contact with Ringling's blue unit elephants at the Tampa Fairgrounds in December 2007/January 2008.

Since 1994, 12 percent of Asian elephants in the U.S. have been diagnosed with a human strain of TB that is transmissible between elephants and humans. After AIDS, TB is the leading infectious cause of adult mortality in the world.

Because of the risk that TB poses to other elephants and the public, please act immediately to determine if elephants on Ringling's blue unit were potentially exposed to TB, ensure that TB-exposed elephants are promptly taken off the road, and ensure that all the elephants receive thorough TB testing.

Please inform me of the USDA's findings. I can be contacted at 312-829-(b)(6) or (b)(6)@peta.org. Thank you for your attention to this matter.

Sincerely,

(b)(6)



cc: Dr. Elizabeth Goldentyer
Dr. Robert Gibbens

(b)(6)

PETA
312-829

(b)(6)

Watch this!



Barbara A
Kohn/MD/APHIS/USDA
04/18/2008 01:27 PM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: Zerbini elephants and public exposure

Was talking about animals..I did tell Chester that we had been working on contact info for a while. No problem with including (b)(6), too, was going to add him to my response, but hit send before I was able to. Perhaps a summary or what we know for Chester (through Betty) may be helpful to him...

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
04/18/2008 01:24 PM

To Barbara A Kohn/MD/APHIS/USDA
cc Ray M Flynn/CO/APHIS/USDA@USDA, tgomez@cdc.gov,
Gregory S Gaj/FL/APHIS/USDA@USDA
Subject Re: Zerbini elephants and public exposure

We've been working with FL and now with MI state vets and/or public health. Are you talking about contact information for people or animals? I think we have a good handle on the animal end of things.

I'm ccing Greg on this as well because I should have had him on the original e-mail.

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care
Barbara A Kohn/MD/APHIS/USDA



Barbara A
Kohn/MD/APHIS/USDA
04/18/2008 11:17 AM

To Denise M Sofranko/NM/APHIS/USDA@USDA
cc Ray M Flynn/CO/APHIS/USDA@USDA, tgomez@cdc.gov
Subject Re: Zerbini elephants and public exposure

Denise -

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Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
04/18/2008 12:28 PM

To tgomez@cdc.gov, Barbara A Kohn/MD/APHIS/USDA
cc Ray M Flynn/CO/APHIS/USDA@USDA
Subject Zerbini elephants and public exposure

Tom and Barb,

We should probably address in some fashion the issue of the TB positive elephant and her public exposure in the last year or so. I'm attaching the itinerary from last year and you can see that they were in Canada for a large portion of it. I've spoken to Ray Flynn about this and we feel that we should let the Canadians know so they can determine if they need to do anything further. We need to let Chester know before we do that and decide who will provide the information.

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What do you guys think?

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

[attachment "2007itin.pdf" deleted by Barbara A Kohn/MD/APHIS/USDA]



Barbara A
Kohn/MD/APHIS/USDA
04/18/2008 01:17 PM

To Denise M Sofranko/NM/APHIS/USDA
cc Ray M Flynn/CO/APHIS/USDA@USDA, tgomez@cdc.gov
bcc
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Sofranko/NM/APHIS/USDA
04/18/2008 12:28 PM

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Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care

[attachment "2007itin.pdf" deleted by Barbara A Kohn/MD/APHIS/USDA]



Barbara A
Kohn/MD/APHIS/USDA
04/14/2008 11:56 AM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: Zerbini elephants 

Will do - won't Anna have a fun time tomorrow when she returns to work!

Barb

Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
04/14/2008 11:50 AM

To Barbara A Kohn/MD/APHIS/USDA
cc
Subject Zerbini elephants 

Barb,

You may already have done this but can you let FWS (just for their information) know that the Zerbini elephant was positive and that Marie and Shelly will probably be going back to MO? They were supposed to go to Canada again this year. I think you have most of the information but let me know if you need more.

thanks!

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care



Barbara A
Kohn/MD/APHIS/USDA
04/09/2008 09:35 AM

To Denise M Sofranko/NM/APHIS/USDA
cc
bcc
Subject Re: Elephant TB Stat Pak: One more time

Denise -

I think the document looks fine - I especially like the last line..... I hope the reviewing group is OK with the result. More work for AC to get procedures together, but I think we could live with the results of the document.

Barb
Denise M Sofranko/NM/APHIS/USDA



Denise M
Sofranko/NM/APHIS/USDA
04/09/2008 09:27 AM

To Thomas O Bunn/IA/APHIS/USDA@USDA
cc Barbara A Kohn/MD/APHIS/USDA@USDA, Charles W
Hench/CO/APHIS/USDA@USDA, Janet B
Payeur/IA/APHIS/USDA@USDA, Jeffrey T
Nelson/IA/APHIS/USDA@USDA, Kathy A
Orloski/CO/APHIS/USDA@USDA, Larry R
Ludemann/IA/APHIS/USDA@USDA, LeeAnn
Thomas/MD/APHIS/USDA@USDA, Paul J
Hauer/IA/APHIS/USDA@USDA, rwaters@nadc.ars.usda.gov
Subject Re: Elephant TB Stat Pak: One more time

Hopefully, I have everyone's comments by now. Please review again and see if this is something we can all agree to send forward. If not, let's discuss again so we can all be comfortable with this.
thanks!

[attachment "Statpakissue409.doc" deleted by Barbara A Kohn/MD/APHIS/USDA]

Denise M. Sofranko, DVM
Field Specialist for Elephants
USDA/APHIS/Animal Care