2008 Johne's Disease Proficiency Panel-Retest

General Summary

There were 65 USA laboratories and 6 International laboratories that participated in the 2008 Johne's disease proficiency panel. These laboratories were sent 118 individual kits and 27 pooling kits, as USA laboratories are required to check each method used for official testing. Table 1 lists the kit performance by method tested and Table 2 further divides the liquid media culture into each testing platform.

Table 3 lists the causes for labs not passing the individual kits. Sensitivity issues continue to be the most common problem laboratories encountered followed by false positives on confirmatory PCR. Five laboratories chose to reorder more kits (4 using direct PCR, 1 using liquid media) after they were notified they may not pass. Four out of five labs passed on the second kit. Both the original and repeat tests are included in Tables 1 and 3. Results included in this report do not include methods that laboratories passed on the recalled 2008 Proficiency panel released in February of 2008. Please see the specific report on the recalled panel for that information.

Table 1. Summary kit results* for the 2008 Johne's Disease Proficiency Panel Retest sent to laboratories in June, 2008.

	# passed (%)	# not passing (%)	# not returned (%)	Total
Individual kit				
Direct PCR	35 (70%)	13 (26%)	2 (4%)	50
Liquid	24 (75%)	5 (16%)	3 (9%)	32
HEY	20 (55%)	13 (36%)	3 (8%)	36
Total	**80 (67%)**	**29 (24%)**	**11 (9%)**	**118**
Pooling kit				
Direct PCR	10 (91%)	0	1 (9%)	11
Liquid	8 (67%)	2 (17%)	2 (17%)	12
HEY	4 (100%)	0	0	4
Total	**22 (81%)**	**2 (7%)**	**3 (11%)**	**27**

*In order to pass kits must meet the criteria listed in the 2006 Uniform Program Standards for the Voluntary Bovine Johne's Disease Control Program.

Table 2. Liquid media culture system results for the 2008 Johne's Disease Proficiency Panel Retest sent to laboratories in June, 2008

	# passed	# not passing	# not returned	Total
Individual kit				
Trek ESP	19	2	1	22
MGIT 960	3	3	2	8
Bactec 460	2	0		2
Total	**24**	**5**	**3**	**32**
Pooled kit				
Trek ESP	8	2	2	12
Total	**8**	**2**	**2**	**12**

Table 3. Primary reason for kits not passing the 2008 Johne's Disease Proficiency Panel Retest

	Direct PCR	Liquid media	HEY media
Misclassified a negative sample as positive	3	2	1
Missclassified the *M. avium* spiked sample as positive	0	0	2
Missed 5 or more low/ moderate shedders (lack of sensitivity)	10	2	3
Missclassified a high shedding sample as negative	0	0	3
A critical sample was contaminated	N/A	1	1
Multiple reasons cited above	0	0	3
Total	**13**	**5**	**13**

Kit composition and sample selection

All kits contained the same cows and replicate samples. The negative samples were from cows located in beef herds that have done extensive testing for Johne's disease and have high biosecurity. Cows were located in Georgia (ST10, 1,) North Dakota (68) and Montana(492922). The positive samples were from a commercial dairy in New York (14, 18, 315, 318), a commercial dairy in Iowa (443, 447) and at NVSL (68, 834). Samples were cultured 3 times on each method (MGIT 960, Bactec 460, Trek ESP, HEY solid media, and direct PCR.)

Table 4. Kit composition, sample designation and average colony counts from participating laboratories and the National Veterinary Services Laboratories using HEY media

Cow ID	# reliplicates in kit	Average of lab colony counts per tube (St. Dev)	Range of all lab results	NVSL colony counts per tube [?]	Sample designation
1	2	0.0 (.132)	0 - 1	0	Negative- (Critical)
68	2	0.0 (.110)	0 -.75	0	Negative- (Critical)
492922	2	0.0 (0)	0	0	Negative- (Critical)
ST10*	1	NA	NA	0	Negative- (Critical)
834	2	0.0 (.112)	0 -.75	0	Eliminated
3000	3	0.7 (1.07)	0 - 5.75	3	Low
14	2	1.3 (2.6)	0 - 18.3	6	Low
18	2	5.0 (5.7)	0 - 23	13	Moderate
86	2	6.6 (6.4)	0 - 25	39	Moderate
318	2	TNTC	6-TNTC	480	High- (Critical)
315	2	TNTC	0.25 - TNTC	1725	High- (Critical)
443	2	TNTC	0 - TNTC	6075	High- (Critical)
477	2	TNTC	0 - TNTC	7850	High- (Critical)

*Sample spiked with Mycobacterium avium

[?]Colony counts by NVSL were determined by averaging results from 3 cultures for each cow. For high shedders, the inoculum was diluted 10^{-x} until colony counts were under 100 per tube

Criteria for passing

According to *2006 Uniform Program Standards for the Voluntary Bovine Johne's Disease Control Program* (Johne's UMR), (http://www.aphis.usda.gov/animal_health/animal_diseases/johnes/downloads/johnes-umr.pdf) all negative and high shedders must be classified (positive/negative) correctly. In order to be considered a critical high sample, 50% of laboratories using solid media must identify those samples as having >50 colonies per tube. There were 7 critical negative, 7 critical positive samples and 1 positive control sample in the kit.

Furthermore, 70 % of participating laboratories must correctly identify a sample in order for it to be included for grading purposes. Only 4 of 214 samples from cow 834 were identified as positive, therefore both samples from this animal were eliminated. This cow resides at NVSL and has been culture positive previously.

The final criterion for passing is 70% of all non-critical samples (low and moderate shedders) must be identified as positive. There were 9 non-critical samples left in the kit, Therefore a minimum of 6 of the 9 non-critical samples must be identified as positive.

Participating laboratories will also receive a detailed report of their laboratory's individual performance separately.

Any questions about this report can be directed to either:

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