

279

12D5.45

Outline of Production

For

**Bursal Disease-Newcastle Disease-Bronchitis Vaccine  
Standard and Variant, Massachusetts and Arkansas Types, Killed Virus**

1,000 Dose - *added*

**Product Code 12D5.45**

**Merial Select, Inc.**  
Gainesville, Georgia 30503 *"USA" deleted*  
U.S. Vet. License No. 279  
*spelled out*

Complete Revision  
September 10, 2002  
Supersedes  
April 30, 1999 ✓

Ref. Code } *added*  
12M5.41

FILED with  
USDA-APHIS-VS  
CENTER FOR VETERINARY  
BIOLOGICS

APR 10 2003

LICENSING & POLICY  
DEVELOPMENT  
NO ENDORSEMENT  
EXPRESSED

**Bursal Disease-Newcastle Disease-Bronchitis Vaccine ✓  
Standard and Variant, Mass. and Ark. Types, Killed Virus ✓  
Product Code 12D5.45 ✓**

U.S. Vet. Lic. No. 279

Page 7

October 24, 2008 ✓  
Supersedes June 06, 2008 ✓

IV. F. Volume of fill.

Fill volume is 500 ml to 520 ml per bottle.

G. Method and technique of filling and sealing final containers.

(b) (4) b

1. The bulk product is contained in a sterile mixing tank.
2. The filling machine is connected with sterile tubing to the mixing tank. Sterile bottles are passed under the fixed filling nozzles.
3. The bottles are sealed with rubber stoppers and aluminum injection-type seals (b)(4)

(b) (4)

H. Desiccation.

Not applicable.

(b) (4)

Amount of antigenic material per dose or doses in final product.

The pre-inactivation titers and approval dates are as follows:

<u>Antigen</u>	<u>Titer per Dose</u>	<u>Approval Date</u>
IBD viruses		
STC	(b)(4)	8/27/92
Variant		8/1/91
NDV	(b)(4)	3/14/94
IBV		6/03/08
		6/03/08

(b)(4)

Each dose of final product will contain not less than 0.008 ml STC IBD and 0.03 ml of Variant E IBD; 0.018 ml of NDV; and 0.024 ml each Mass. and Ark. IBV.

*pl. i chgs not made as stated in [unclear]*

(b)(4)

V. Testing.

Bulk samples or final container samples of each serial and subserial may be tested at either licensed facility in Berlin, MD, or Gainesville, GA, and must meet the following criteria:

(b)(6)

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BIOLOGICS

DEC 05 2008

POLICY, EVALUATION, AND LICENSING  
NO ENDORSEMENT  
EXPRESSED

#6 of 3

11-15-08

(b) (4)

**Bursal Disease-Newcastle Disease (b) (4)  
Standard and Variant, Mass. and Ark. Types, Killed Virus  
Product Code 12D5.45**

U.S. Vet. Lic. No. 279

Page 8

July 7, 2003  
Supersedes September 10, 2002

V. A. Purity.

(b) (4)

1. Final container samples of each serial and subserial will be tested (b)(4) as described in (b)(4).

a. For the detection (b)(4), 1 ml of product

b. For the detection (b) (4) (b)(4)

2. Bulk samples of each viral harvest are tested for (b)(4) to (b)(4)

3. The (b) (4)

4. The bulk harvest of IBD, NDV, and IBV (b)(4) in accordance (b)(4), as approved by USDA on June 25, 2003.

5. Each bulk harvest of bronchitis and bursal disease (b)(4) is tested for (b)(4)

B. Safety.

1. (b)(4) test will constitute the safety test.

2. (b)(4)

3. (b)(4)

(b)(6)

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DEVELOPMENT  
NO ENDORSEMENT  
EXPRESSED

9-03

#6

**Bursal Disease-Newcastle Disease-Bronchitis Vaccine  
Standard and Variant, Mass. and Ark. Types, Killed Virus  
Product Code 12D5.45**

U.S. Vet. Lic. No. 279

Page 9

May 14, 2004  
Supersedes September 10, 2002

V. C. Potency.

[redacted] (b)(4)

1. IBD viruses.

In accordance with [redacted] (b)(4) conditions, the test is [redacted]  
[redacted] (b)(4)

2. NDV.

[redacted] (b)(4)

3. IBV.

Potency test is conducted according to [redacted] (b)(4). In this test, the  
[redacted] (b)(4)  
[redacted] (b)(4).

D. Moisture.

Not applicable. ✓

E. Additional tests. ✓

1. Pre-inactivated IBD bulk samples shall be tested for [redacted] (b)(4)  
[redacted] (b)(4)

2. [redacted] (b)(4) is tested as specified [redacted] (b)(4) and  
[redacted] (b)(4)

[redacted] (b)(4)

VI. Post-preparatory steps.

Final product may be shipped to the Gainesville, Georgia, facility for labeling and final packaging.  
Shipment will be by refrigerated truck. ✓

(b)(6)  
[redacted]

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MAY 18 2004

POLICY, EVALUATION, AND LICENSING  
NO ENDORSEMENT  
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Special Outline No. 63

(b) (4)

(b) (4)

Bursal Disease Vaccines,  
Killed Virus Testing for CAV Contamination

**Merial Select, Inc.**  
Gainesville, GA 30503  
U.S. Vet. License No. 279

New Outline  
April 6, 2001

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LICENSING & POLICY  
DEVELOPMENT  
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(b) (4)

Special Outline No. 63

(b)(4) Bursal Disease Vaccines,  
Killed Virus Testing for CAV Contamination

U.S. Vet. License No. 279

Page 1

April 6, 2001

New

I. Materials.

A. Pre-inactivated bulk samples.

(b) (4)

Pre-inactivated bulk samples will be tested for the

(b) (4)

(b) (4)

B. Reagents.

1. (b) (4)
2. (b) (4)
3. (b) (4)
4. (b) (4)

II. Methods.

A. (b) (4)

- (b)(4)

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JUL 19 2001

LICENSING & POLICY  
DEVELOPMENT  
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EXPRESSED

Special Outline No. 63  
(b)(4) Origin Bursal Disease Vaccines,  
Killed Virus Testing for CAV Contamination

U.S. Vet. License No. 279

(b) (4)

- II. A. 8. (b)(4)
- 9. (b)(4)
- (b)(4)
- 10. (b)(4) (b) (4)
- (b)(4)
- 11. (b)(4)

B. Detection of CAV.

space ?

Follow (b) (4)  
(b)(4)

III. Analysis.

- A. (b)(4)  
If the b4 CAV b4  
b4 If the test is a b4  
the test b4

- B. b4  
(b)(4)  
(b)(4)
- 1. (b)(4)  
(b)(4)
- 2. (b)(4)

b6

New-checked: format, grammar, spelling  
and readability

Supported by Research Report CAV-0101  
JUL 19 2001

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LICENSING & POLICY  
DEVELOPMENT  
NO ENDORSEMENT  
EXPRESSED

05-01-01

#6 gpc

test 279

S.O.#100

**Special Outline No. 100**

**Detection of Avian Lymphoid Leukosis**

**Merial Select, Inc.**

[Gainesville, GA 30503] - added  
U.S. Vet. License No. 279

Complete Revision  
March 14, 2002  
Supersedes  
January 27, 1999

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JUL - 9 2002

LICENSING & POLICY  
DEVELOPMENT  
NO ENDORSEMENT  
EXPRESSED

Special Outline No. 100  
Detection of Avian Lymphoid Leukosis

U.S. Vet. Lic. No. 279

Page 1

March 14, 2002  
Complete Revision

I. Purpose.

(b) (4)

*added* - Final container vaccine or bulk virus material is tested following (b) (4)

accordance (b) (4)

II. Procedure.

A. (b) (4) cultures are prepared (b) (4)  
according (b) (4)

*added* ✓

B. (b) (4)  
Five 60mm or two 100mm dishes are prepared per test sample.

*revised* C. (b) (4)

*revised* D. For each test session or series, (b) (4) controls are maintained. (b) (4)  
A Lymphoid Leukosis virus and (b) (4) Lymphoid Leukosis virus are used as (b) (4)  
(b) (4). A (b) (4) is designated as the (b) (4). All test  
samples (b) (4)

*revised* E. Maintenance of each test sample is done in accordance with (b) (4)

*revised* F. The test material (b) (4) using a (b) (4) during  
a (b) (4) (b) (4) and a (b) (4) the  
(b) (4) E

(b) (4)

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JUL - 9 2002

LICENSING & POLICY  
DEVELOPMENT  
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*Not on Sum. of Chg.*



Est: 279  
S.O. #105

Est. 279  
S.O. 105

Special Outline No. 105

Potency Test for Mass. and Ark. Bronchitis Virus Vaccine, Killed Virus

Merial Select, Inc.  
Gainesville, GA 30503  
U.S. Vet. License No. 279

Complete Revision  
May 30, 2003  
Supersedes  
May 21, 1998

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CENTER FOR VETERINARY  
BIOLOGICS

JUL 30 2003

LICENSING & POLICY  
DEVELOPMENT  
NO ENDORSEMENT  
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Special Outline No. 105  
Potency Test for Mass. and Ark. Bronchitis Virus Vaccine, Killed Virus

U.S. Vet. Lic. No. 279

Page 1

May 30, 2003  
Complete Revision

I. Purpose.

This is a procedure for determining the potency of killed bronchitis vaccines for poultry. The basic protocol is as follows:

(b) (4)

(b) (4) from (b) (4) in the final product. (b) (4)

II. Linkage to efficacy.

This procedure was conducted using (b) (4)

(b) (4)

(b) (4)

(b) (4)

Mass. strain

(b) (4)

(b) (4)

Ark. strain

(b) (4)

(b) (4)

For (b) (4) Ark. vaccinates be (b) (4) those (b) (4)

III. Materials.

A. Animals.

(b) (4)

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LICENSING & POLICY  
DEVELOPMENT  
NO ENDORSEMENT  
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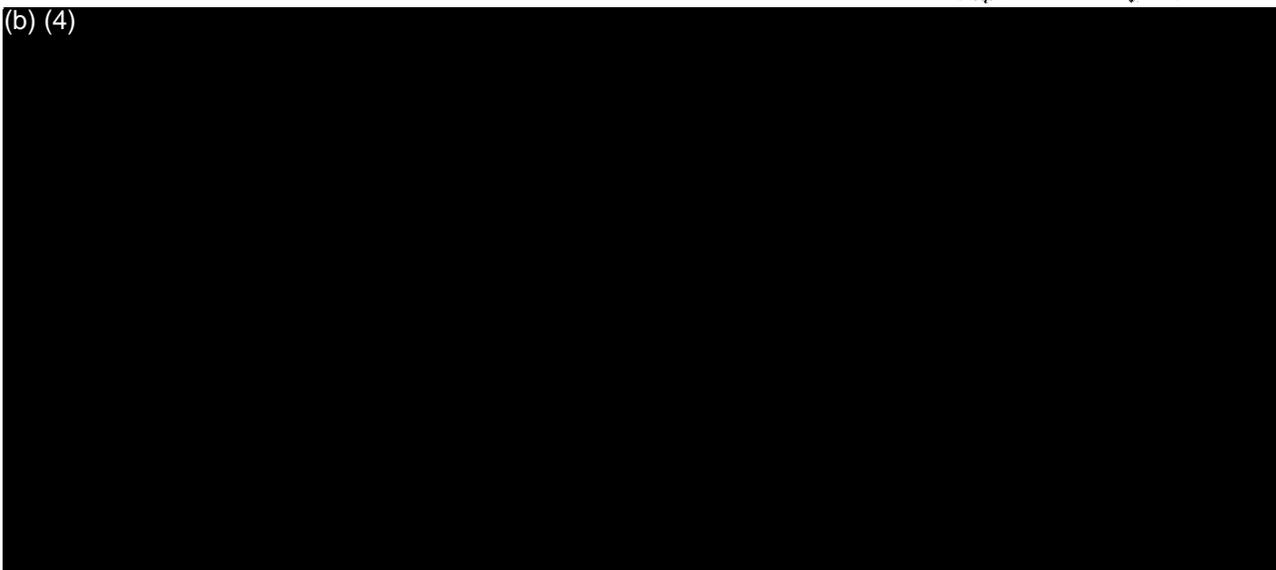
Special Outline No. 105 ✓  
Potency Test for Mass. and Ark. Bronchitis Virus Vaccine, Killed Virus ✓

U.S. Vet. Lic. No. 279 ✓

Page 2

October 24, 2008 ✓  
Supersedes May 30, 2003 ✓

(b) (4)



IV. Methods.

(b) (4)



(b)(6)  
(b)(6)  
(b)(6)

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POLICY, EVALUATION, AND LICENSING  
NO ENDORSEMENT  
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9/28  
11-14-08

Special Outline No. 105  
Potency Test for Mass. and Ark. Bronchitis Virus Vaccine, Killed Virus

U.S. Vet. Lic. No. 279

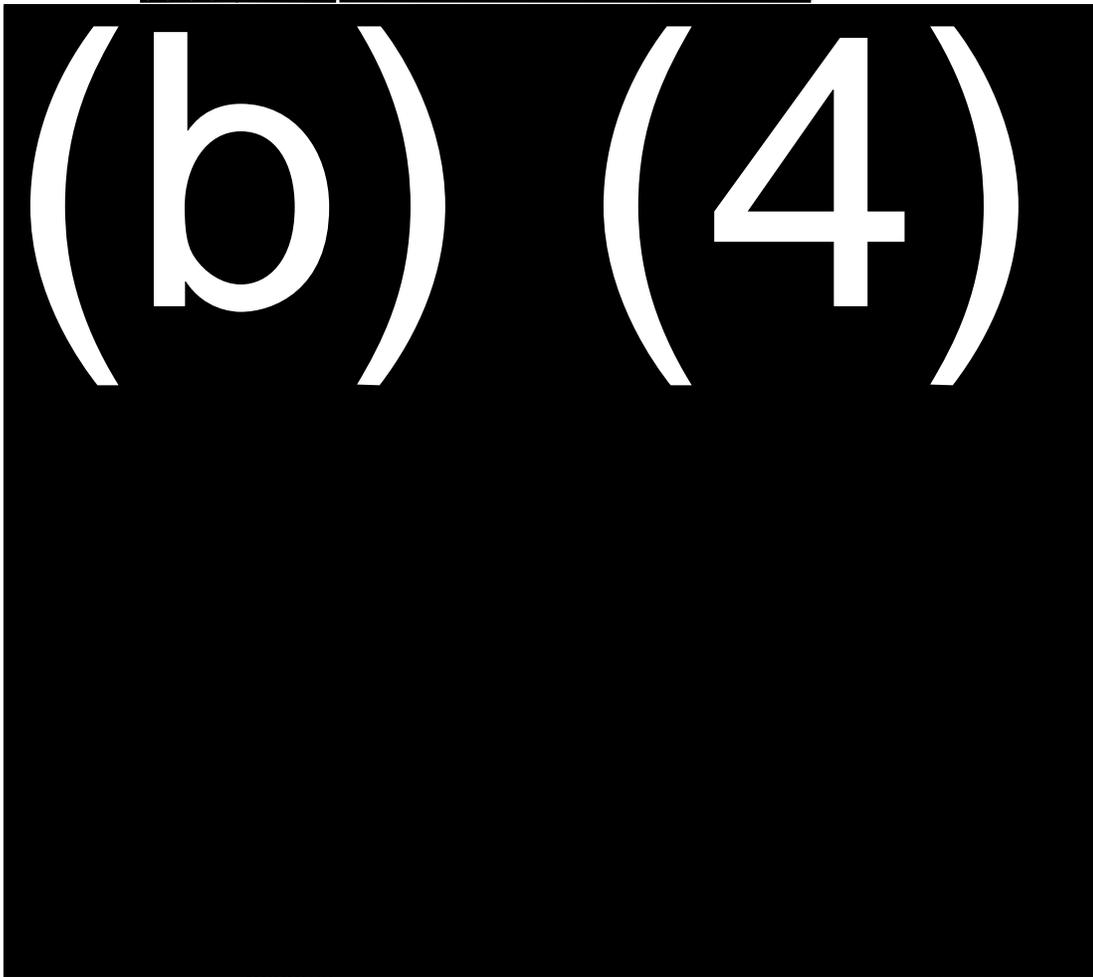
Page 3

May 30, 2003 ✓  
Complete Revision

IV. B. (b) (4)

For the Mass. (b) (4) and for the Ark. (b) (4)

1. The (b) (4)  
(b) (4)



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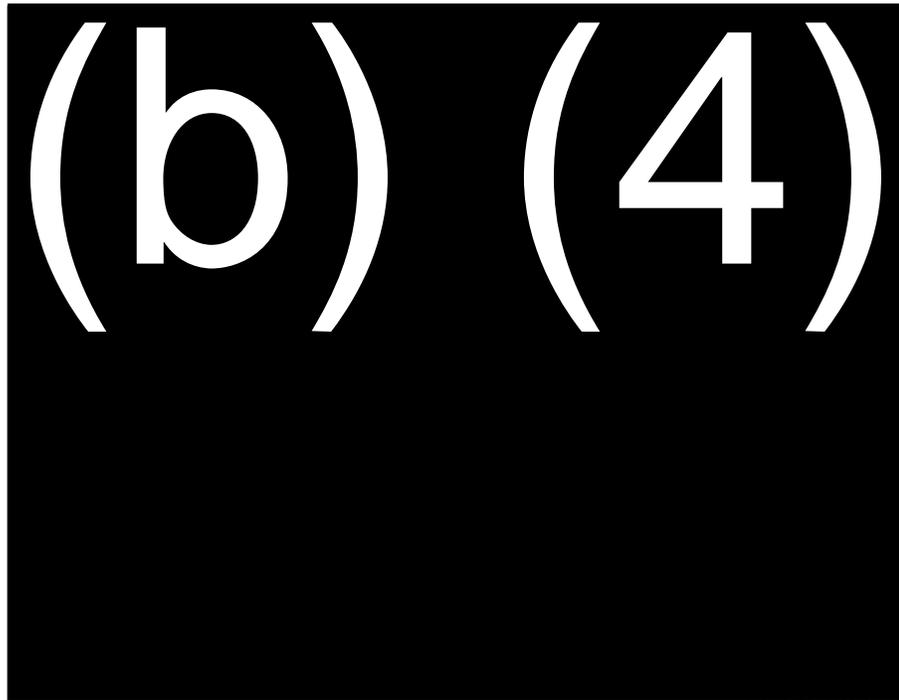
Special Outline No. 105  
Potency Test for Mass. and Ark. Bronchitis Virus Vaccine, Killed Virus

U.S. Vet. Lic. No. 279

Page 4

May 30, 2003  
Complete Revision

- IV. B. 2. h. The plates (b) (4)
3. Evaluation of (b) (4) test.
- a. The HA (b) (4)
- b. (b) (4)
4. Hemagglutination inhibition test.



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DEVELOPMENT  
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Special Outline No. 105  
Potency Test for Mass. and Ark. Bronchitis Virus Vaccine, Killed Virus

U.S. Vet. Lic. No. 279

Page 5

May 30, 2003  
Complete Revision

IV. B. 4. e.

For the Mass. (b) (4) <sup>0.5</sup> three to <sup>3</sup>

For the Ark. (b) (4) <sup>0.5</sup> three <sup>3</sup>

f. (b) (4) one

(b) (4)

g. (b) (4)

h. (b) (4) of

i. (b) (4)

j. (b) (4)

5. Back titration.

a. (b) (4)

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LICENSING & POLICY  
DEVELOPMENT  
NO ENDORSEMENT  
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Special Outline No. 105  
Potency Test for Mass. and Ark. Bronchitis Virus Vaccine, Killed Virus

U.S. Vet. Lic. No. 279

Page 6

October 24, 2008  
Supersedes May 30, 2003

IV. B. 5. b.

(b) (4)

V. Results.

A. For a satisfactory test the following should occur.

1. (b) (4)
2. (b) (4)
3. (b) (4) satisfy the criteria in section

B. For the test to be satisfactory for serial release (b) (4)

(b) (4)

[Redacted]

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NOV 17 2008

POLICY, EVALUATION, AND LICENSING  
NO ENDORSEMENT  
EXPRESSED

*8/28  
11-14-08*

279  
12P5.40

Outline of Production

For

**Bursal Disease-Newcastle Disease-Reovirus Vaccine,  
Standard and Variant, Killed Virus**

1,000 Doses - added

**Product Code 12P5.40**

**Merial Select, Inc.**  
Gainesville, Georgia 30503 "USA" deleted  
U.S. Vet. License No. 279

Complete Revision  
September 10, 2002  
Supersedes  
May 16, 2001 ✓

Ref. Code } added  
12M5.41

FILED FOR  
LICENSING & POLICY  
DEVELOPMENT  
CENTER FOR VETERINARY  
BIOLOGICS

APR 11 2003

LICENSING & POLICY  
DEVELOPMENT  
NO ENDORSEMENT  
EXPRESSED

Bursal Disease-Newcastle Disease-Reovirus Vaccine,  
Standard and Variant, Killed Virus  
Product Code 12P5.40

(b) (4)

U.S. Vet. License No. 279

Page 7

September 10, 2002  
Complete Revision

(b)

IV. G. Method and technique of filling and sealing final containers.

1. The bulk product is contained in a sterile mixing tank.
2. The filling machine is connected with sterile tubing (b) (4) mixing tank. Sterile bottles are passed under the fixed filling nozzles (b) (4).
3. The bottles are sealed with rubber stoppers and aluminum injection type seals (b) (4).

H. Desiccation.

(b) (4)

Not applicable.

I. Amount of antigenic material per dose or doses in final product.

The pre-inactivation titers and approval dates are as follows:

<u>Antigen</u>	<u>Titer per Dose</u>	<u>Approval Date</u>
IBD viruses STC Variant	(b)(4)	(b)(4)
NDV (b)(4)	(b)(4)	(b)(4)
Avian Reoviruses (b)(4)	(b)(4)	(b)(4)

Each dose of final product will contain (b)(4) IBD and (b)(4) Variant (b)(4) of NDV; and 0 (b)(4) ml each of the Reoviruses.

V. Testing.

Bulk samples or final container samples of each serial and subserial may be tested at either licensed facility in Berlin, MD, or Gainesville, GA, and must meet the following criteria:

APR 1 2003

(b) (4)

(b) (4)

**Bursal Disease-Newcastle Disease-Reovirus Vaccine,  
Standard and Variant, K (b) (4)  
Product Code 12P5.40**

U.S. Vet. License No. 279

Page 8

July 7, 2003  
Supersedes September 10, 2002

V. A. Purity.

1. Final container samples of each serial and subserial will be tested for (b) (4)

a. For the detection (b) (4)

b. For the detection (b) (4) 1 ml of product is

2. Bulk samples of each viral harvest shall be tested for (b) (4)

3. (b) (4)

4. (b) (4) The bulk harvest of IBD, NDV, and Reovirus shall be exempt from mycoplasma (b) (4) as approved by USDA on June 25, 2003

5. Each bulk harvest of bursal disease, and Reovirus (b) (4) is tested for (b) (4)

B. Safety.

1. Observation (b) (4)

2. (b) (4)

3. (b) (4)

b6

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AUG 28 2003

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DEVELOPMENT  
NO ENDORSEMENT  
EXPRESSED

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**Bursal Disease-Newcastle Disease-Reovirus Vaccine,  
Standard and Variant, Killed Virus  
Product Code 12P5.40**

(b) (4)

U.S. Vet. License No. 279

Page 9

(b)(4)

May 17, 2004

Supersedes July 7, 2003

V. C. Potency.

(b) (4)

1. IBD viruses.

(b) (4)

(b)(4)

2. NDV.

(b)(4)

3. Avian Reoviruses.

See (b)(4) for details. In this test, (b)(4)

D. Moisture.

Not applicable.

E. Additional tests.

1. Pre-inactivated IBD bulk samples shall be tested (b)(4) (b)(4) Special Outline

2. (b)(4) is tested as specified (b)(4) (f) and must (b)(4)

VI. Post-preparatory steps.

Final product may be shipped to the Gainesville, Georgia, facility for labeling and final packaging. Shipment will be by refrigerated truck.

A. Form and size of containers in which the product is to be distributed.

1. Final product container – refer (b)(4) (b)(4)

2. The product is marketed in cartons of ten 500 ml bottles, each containing 1,000

b6

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MAY 20 2004

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NO ENDORSEMENT  
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(b) (4)

Est. 279  
S.O. #104

Est 279  
S.O. 104

Special Outline No. 104

Potency Test for Avian Reovirus Vaccine, Killed Virus

Merial Select, Inc.  
Gainesville, GA 30503 - *Labeled*  
U.S. Vet. License No. 279 -  
*Special Outline*

Complete Revision  
May 30, 2003 -  
Supersedes  
May 28, 1998  
*21 - Should be*

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BIOLOGICS

JUL 30 2003

LICENSING & POLICY  
DEVELOPMENT  
NO ENDORSEMENT  
EXPRESSED

*Initiated  
7/9/03*

**Special Outline No. 104  
Potency Test for Avian Reovirus Vaccine, Killed Virus**

U.S. Vet. Lic. No. 279

Page 1

May 30, 2003  
Complete Revision

**I. Purpose.**

This is a procedure for determining the potency of killed reovirus vaccines for b4 The basic protocol is as follows:

(b) (4)

[Redacted]

**II.**

b4

(b) (4)

**III.**

**Materials.**

(b)(4)

*did*

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BIOLOGICS

JUL 30 2003

LICENSING & POLICY  
DEVELOPMENT  
NO ENDORSEMENT  
EXPRESSED

Special Outline No. 104  
Potency Test for Avian Reovirus Vaccine, Killed Virus

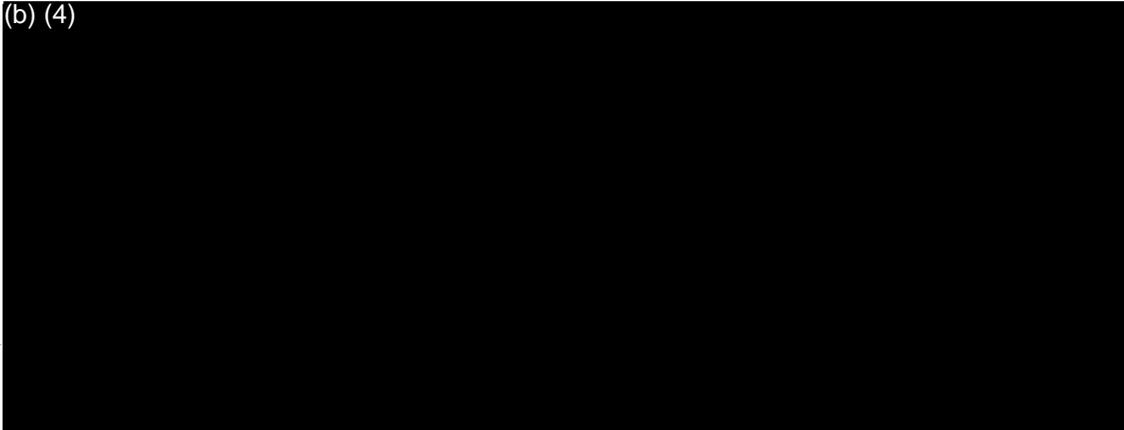
U.S. Vet. Lic. No. 279

Page 2

May 30, 2003  
Complete Revision

III. D.

(b) (4)

A large black rectangular redaction box covers the majority of the page content under section III. D.

IV. Methods.

(b) (4)

A large black rectangular redaction box covers the entire content of section IV. Methods.

USDA-APHIS-VS  
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JUL 30 2003

LICENSING & POLICY  
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NO ENDORSEMENT  
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(b) (4)

Special Outline No.  
Potency Test for Avian Reovir

U.S. Vet. Lic. No. 279

Page 3

IV. B.

b4

b4

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BIOLOGICS

JUL 30 2003

LICENSING & POLICY  
DEVELOPMENT  
NO ENDORSEMENT  
EXPRESSED

(b) (4)

Potency Tes

U.S. Vet. Lic. No. 279 ✓

IV. B. [Redacted]

V. Results.

A. For a satisfactory tes

(b) (6)

B.

neu

(b)(6)

b4

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BIOLOGICS

NOV 18 2008

POLICY, EVALUATION, AND LICENSING  
NO ENDORSEMENT  
EXPRESSED

11-14-08

Est. 279  
1701.10

Outline of Production

For

**Newcastle Disease Vaccine  
VG/GA Strain, Live Virus**

Product Code No. 1701.10 *per P&I*

(10,000 Doses Frozen) Vaccine  
*added*

**Merial Select, Inc.**

Gainesville, Georgia 30503

U.S. Vet. License No. 279

Complete Revision

December 16, 2008

Supersedes

✓ December 3, 2002

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MAR 31 2009

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NO ENDORSEMENT  
EXPRESSED

*added to  
each page*

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(b) (4)

Newcastle Disease Vaccine  
VG/GA Strain, Live Virus  
Product Code No. 1701.10

The final product is stored in a liquid nitrogen freezer.

I. Amount of antigenic material per dose or doses in final container.

Each dose of final product shall contain (b)(4) of Newcastle disease (b)(4)

(b)(4)

V. Testing.

Bulk samples or final container samples of each serial and (b) (4) licensed facility in Berlin, MD, or Gainesville, GA, and must meet the following criteria.

A. Purity.

1. Final container samples of each serial and subserial shall be tested for (b)(4) (b)(4)

(b)(4)

a. For detection of (b)(4) in final containers, (b)(4) product is (b)(4)

b. For the detection (b)(4) in final containers, (b)(4)

2. Final container samples (b) (4)

3. Bulk samples of each viral harvest shall be tested for b4 according to b4 b4

4. Final container samples of each serial or subserial shall be tested for (b)(4) (b)(4)

5. Final container samples of each serial or subserial shall be tested (b)(4) (b)(4)

B. Safety.

(b)(4)

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MAR 23 2009

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Newcastle Disease (b) (4)  
VG/GA Strain, Live Virus  
Product (b) (4)

U.S. Vet. Lic. No. 279

Page 10

December 16, 2008  
Complete Revision

V. C. Potency.

The potency tests are conducted according to (b) (4) ✓

(b) (4) added ✓

The minimum virus titer shall be (b) (4)

(b) (4)

1.

(b) (4)

The results of this test were USDA approved on July 17, 1991.

2.

For serial release, (b) (4)

(b) (4)

Moisture.

Not applicable.

E. Identity test.

The (b) (4) test shall be conducted on final container samples as prescribed in

(b) (4)

VI. Post-preparatory steps.

Each serial or subserial shall be packaged at the facility at which the final product is produced.

A. Form and size of final containers in which the product is to be distributed.

1. The final product is marketed 10,000 doses per 2.0 ml heat-sealed glass ampule (Special Outline No. 30).
2. Five ampules are placed in each aluminum cane. The canes are stored and distributed in liquid nitrogen.
3. For drinking water and coarse spray administration, the vaccine is supplied without diluent.

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Distribute and disclose only on a need to know basis.  
Property of Merial Select, Inc.

Est. 279  
S.O. #43

279  
S.O. #43

Special Outline No. 43

Method for the Titration and Identity Tests for  
Newcastle Disease and Infectious Bronchitis Viruses

Merial Select, Inc.  
Gainesville, GA 30503 - from 30501 ✓  
U.S. Vet. License No. 279

Complete Revision  
November 5, 2004  
Supersedes  
November 9, 1998, ✓

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(b) (4)

Special Outline No. 43  
Method for the Titration and Identity Tests for  
Newcastle Disease and Infectious Bronchitis Viruses

U.S. Vet. Lic. No. 279

Page 1

November 5, (b) (4)

I. Potency testing for final product, bulk virus, or Master Seed

A. Final product titrations.

1. Newcastle disease (ND) vaccine.

Frozen or lyophilized ND vaccine

(b)(4)

Tenfold serial dilutions  $10^{-1}$  through  $10^{-9}$  of the reconstituted vaccine are made by

(b)(4)

2. Infectious bronchitis (IB) vaccine.

(b)(4)

(b)  
(4)

3. Combination ND/IB vaccine.

The ND/IB vaccine is prepared

(b)(4)

volume of  
tempe

(0.6ml) deleted ✓

B. Bulk virus or MSV titrations.

1. NDV.

(b)(4)

(b)(4)

from to a total ✓  
... Table 1" →

from 6" ✓  
Table 1 deleted ✓ →

added ✓

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NOV 19 2004

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Special Outline No. 43  
Method for the Titration and Identity Tests for  
Newcastle Disease and Infectious Bronchitis Viruses

U.S. Vet. Lic. No. 279

Page 2

November 5, 2004  
Complete Revision

I. B. 2. IBV.

(b)(4)

(b)

II. Identity tests.

Note: Virus identity tests are (b) (4)

A. Final product identity.

For ND, IB, or ND/IB vaccine:

1.

2.

B. Bulk virus or MSV identity.

(b) (4)

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(b) (4)

Method for the Titration and Identity Tests for  
Newcastle Disease and Infectious Bronchitis Viruses

(b) (4)

U.S. Vet. Lic. No. 279

Page 3

January 23, 2009

Supersedes November 5, 2004

III.

(b)(4)

(b) (4)

A. Final product titrations.

1. NDV inoculation.

(b) (4)

(b)(4)

B. Bulk virus or MSV titrations.

(b)(4)

C. Final product identity

For NDV, IBV and N/B

(b)(4)

five (5)

indicated (15 eggs total)

D. Bulk virus or MSV identity.

(b)(4)

b6

UNITED STATES  
DEPARTMENT OF AGRICULTURE  
CENTERS FOR EPIDEMIOLOGY AND PREVENTION  
DIVISION OF FIELD OPERATIONS

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2/6/09

Special Outline No. 43  
Method for the Titration and Identity Tests for  
Newcastle Disease and Infectious Bronchitis Viruses

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Page 4

November 3, 2005

Supersedes November 5, 2004

(b) (4)

V. Interpretation of results.

A. NDV.

(b) (4)

B. IBV.

(b) (4)

*added per*

VI. Calculations.

A. Final product calculations.

1. NDV or IBV vaccine.

(b) (4)

(b) (6)

(b) (4)

#6  
*[Signature]* 08/Nov/05

*Lab 11-06-05*

FIELD UNIT  
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(b) (4)

Special Out (b) (4)  
Method for the Titration (4)  
Newcastle Disease and Infe

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Page 5

November 3, 2005  
Supersedes November 5, 2004 ✓

VI. A. 2. Combination N/B vaccine.

a. NDV fraction.

See Section VI. A. 1.

b. IBV fraction.

(b)(4)

B. NDV or IBV viral bulk virus or MSV titrations.

(b)(4)

C.

(b)(4)

D. NDV or IBV bulk virus or MSV identity.

(b)(4)

b6

*MB 11-08-05*

*B6  
08/Nov/05*

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NOV 15 2005

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Est. 279  
Code 1711.10

Outline of Production ✓

For ✓

Newcastle Disease Vaccine ✓  
B1 Type, B1 Strain, Live Virus ✓

Product Code No. 1711.10 ✓

1,000, 2,000, 5,000, 15,000 and 25,000 Doses (Lyophilized Vaccine) *Address*

(b) (4)



*Merial Select Laboratories, Inc.*  
Merial Select, Inc. *30501*  
Gainesville, GA 30503 *30501*  
U.S. Veterinary License No. 279  
*Spelled Out*

Complete Revision ✓  
June 30, 2003 ✓  
Supersedes  
February 18, 1997 ✓

Ref. Code  
17A2.10  
*Address*

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AUG 28 2003

LICENSING & POLICY  
DEVELOPMENT  
NO ENDORSEMENT  
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(b) (4)

(b) (4)

(b)(4)

Newcastle Disease Vaccine  
B1 Type, B1 Strain, Live Virus  
Product Code No. 1711.10

U.S. Vet. Lic. No. 279

Page 6

(b)(4)

December 16, 2008  
Supersedes March 9, 2000

V. Testing.

Bulk samples or final container samples of each serial and subserial may be tested at either licensed facility in Berlin, Maryland, or Gainesville, Georgia (b)(4)

A. Purity.

1. Final container samples of each serial or subserial shall be tested for (b)(4)  
(b)(4)

a. For detection (b)(4)

b. For detection (b)(4)

2. Final container samples of each serial or subserial shall be tested for (b)(4)

3. Bulk suspension samples shall be collected and tested for (b)(4)

4. Final container samples of each serial or subserial shall be tested (b)(4)

5. Final container samples of each serial or subserial shall be tested (b)(4)

B. Safety.

Final container samples of each serial or subserial shall be tested for safety (b)(4)

C. Potency.

The potency test is conducted (b)(4)

*Missing  
Dilution of  
Preceding*

*Added*

b6

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*8/12-24*

*#6  
4/3*

Newcastle Disease Vaccine  
B1 Type, B1 Strain, Live Virus  
Product Code No. 1711.10

U.S. Vet. Lic. No. 279

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April 16, 2009 ✓  
Supersedes June 30, 2003 ✓

V. C. 1.

(b)(4)

The results were approved on January 11, 1984.

2.

(b)(4) started on January 7, 1982 and concluded  
February 11, (b)(4)  
The results were approved on  
February 25, 1982.

D. Moisture.

Not applicable.

E. Identity.

(b)(4)

test shall be conducted on final product.

(b)(4)

(b)(4)

Preparatory steps.

Product may be shipped to the Gainesville, Georgia, licensed facility for labeling and final  
ing. The product will be crimp sealed with the serial number stamped on each seal and  
labeled taskets. Shipment will be by refrigerated truck.

(b)(4)

A. Form and size of final containers in which the product is to be distributed.

1. The final product is marketed in cartons of ten or fifty 3 ml vials or twenty-five 10 ml vials each containing 1,000 or 2,000 doses; twenty-five 10 ml vials each containing 5,000 doses; ten 20 ml vials each containing 15,000 doses; a single vial package containing 25,000 doses, or a carton containing fifteen 50 ml vials each containing 25,000 doses.

(b)(4)

2. For distribution in Columbia, the product must have a  
pe (b)(4)

3. For distribution in Brazil, the product must have

(b)(4)

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#6  
4/13

5/4/09