

Code: 9240.D0

Est: 298
Code 9240.D0



BRA-RG-228 ✓

Version 1 ✓

OUTLINE OF PRODUCTION

CANINE MELANOMA VACCINE, DNA ✓

PRODUCT CODE 9240.D0 ✓

MERIAL, INC.

115 TRANSTECH DRIVE

ATHENS, GEORGIA 30601 ✓

Deleted Phone and Fax Numbers

ESTABLISHMENT LICENSE NO. 298

DATE: 16 AUGUST 2006 ✓

SUPERSEDES: 05 AUGUST 2005 ✓

COMPLETE REVISION ✓

FILED with
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Merial, Inc. License No. 298 Athens, Georgia	CANINE MELANOMA VACCINE, DNA Product Code 9240.D0	BRA-RG-228 Version 1
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Page 1

Date: 16 August 2006 ✓
Supersedes: Complete Revision

I. COMPOSITION OF THE PRODUCT

A. Microorganisms Used:

1. Identification of the Microorganisms including Strains or Isolate:

The microorganism used is an *Escherichia coli* vector containing a plasmid carrying the gene for human tyrosinase. The strain is identified as (b) (4)

(b) (4)

2. Isolation and Passage History of Each Microorganism:

Original starting seed material, identified as (b) (4) was provided by (b) (4) to Merial, Inc. (License No. 298, Athens, Georgia), for preparation of a (b) (4) seed. The host organism was an *E. coli* strain (b) (4) sourced from (b) (4). The (b) (4) was prepared by (b) (4) under GMP conditions in accordance with FDA guidelines. The (b) (4) was then (b) (4) (b) (4) in the presence of (b) (4). The (b) (4) (b) (4) was prepared using (b) (4) was (b) (4) to Merial, Inc. (License No. 298), under USDA Import Permit (b) (4) 27 January 2004 and was subsequently (b) (4) (b) (4), on 01 April 2004.

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I. A. 2. Continued

(b) (4) generated a (b) (4) provided by Merial, into a (b) (4) (b) (4) (b) (4). This seed, (b) (4), (b) (4) was sent to Merial, Inc., License No. 298, on 04 May 2004. This seed, (b) (4), was then exported to (b) (4) (b) (4), on 10 May 2004, under Accompanying Document # (b) (4).

(b) (4) (b) (4) and then was (b) (4)

(b) (4) Seed was (b) (4) (b) (4) using (b) (4) (v/v). This (b) (4) seed was labeled (b) (4) (b) (4) Merial, Inc., License No. 298, (b) (4) on 30 September 2004, under USDA APHIS Import Permit #52232. (b) (4) seed was produced from this (b) (4) seed in (b) (4) (b) (4) (b) (4) and (b) (4) on 08 October 2004 at (b) (4) (b) (4) The (b) (4) seed is identified on the stored container labels of (b) (4) seed and the firm's records as (b) (4) (b) (4) were submitted by Merial, Inc., License No. 298, to USDA-APHIS and approved for use on 17 January 2006. - added ✓

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I. B. Source and Date of Accession of Each Microorganism:

Merial, Inc., License No. 298, Athens, Georgia, prepared the (b) (4)

(b) (4)

C. Strains:

(b) (4), carrying the gene for human tyrosinase.

D. Proportion of Each Strain:

N/A

II. CULTURES

A. Identification of Each Microorganism and Frequency of Methods of Identification:

1. The identity of the culture is identified at (b) (b) (4) seed level using (b) (4)

2. The identity of the (b) (4) from (b) (4) from the (b) (4) level was confirmed by (b) (4). A vial of (b) (4)

(b) (4)

and were (b) (4)

(b) (4) in a flask. The

(b) (4) was (b) (4) and (b) (4) g of the (b) (4) was

performed by (b) (4) using a (b) (6)

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II. A. 2. Continued

(b) (4)
[Redacted]

3. The identity (b) (4), at the level of the (b) (4) (Section IV.C.7), shall be confirmed (b) (4)
[Redacted]
[Redacted] with acceptance criteria described (b) (4) 8.b This procedure shall be performed on each (b) (4)

B. Virulence, Purity, Maintenance, and Range of Cultures:

1. Virulence:

N/A

2. Purity:

The (b) (4) seed, working seeds, and each culture used for production are checked for purity by (b) (4).

3. Maintenance:

(b) (4)

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II. B. 4. Range:

(b) (4)

The culture used for (b) (4)
from the (b) (4) seed, which is the number of passages used in the (b) (4).

C. Composition and Reaction of Media Used for (b) (4) Cultures:

(b) (4)

(b) (4) in cultures are grown on (b) (4)
(b) (4)
(b) (4) (b) (4) (b) (4)
(b) (4)
(b) (4)
(b) (4)

D. Character, Size, and Shape of Containers Used for Growing Cultures:

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spacing

1. (b) (4) cultures are grown in a volume of (b) (4) constituting (b) (4) of (b) (4)
(b) (4) plastic vessels or (b) (4) steel vessels (b) (4)

revised

2. (b) (4) in a volume (b) (4) constituting (b) (4) (b) (4)
added

E. Storage Conditions (b) (4) Cultures:

(b) (4) and (b) (4) cultures are (b) (4) with (b) (4)
(b) (4). The (b) (4) seed is obtained by (b) (4)
(b) (4) from the (b) (4) seed.

(b)(6)

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II. F. Methods of Preparing Suspensions for Seeding and Inoculation:

(b) (4)

The seed (b) (4) (b) (4) (b) (4) After incubation

(b) (4) a loopful of colonies inoculates (b) (4) culture in an erlenmayer flask

(b) (4) and (b) (4) are carried out (b) (4) n of the (b) (4)

(b) (4) at a rate of (b) (4) of the medium volume.

G. Technique of (b) (4) :

Cultures are (b) (4) by means of sterile loops (from first plate culture), pipetting (between flasks), or by using a sterile transfer hose using tank pressure or peristaltic pump (into fermenters).

H. Period of Time, Conditions, and Temperature of Incubation:

1. All cultures are incubated at (b) (4) hours depending upon passage level and culture volume. Liquid cultures will be (b) (4) as required for growth.

2. (b) (4) into the (b) (4)

3. Production culture pH is controlled (b) (4)

4. (b) (4) are present in the (b) (4) (b) (4) added (b) (4) to support continuing (b) (4)

(b) (4) a. (b) (4) is initiated at (b) (4) (b) (4) as indicated by an (b) (4)

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II. H. 4. b. (b) (4) is added (b) (4) achieve (b) (4)
(b) (4)

I. Characteristics and Amount of Growth:

1. Cultures are examined for purity by (b) (4)
2. The amount of growth is determined (b) (4) ^{added ✓} using a
(b) (4) must attain an (b) (4)
a (b) (4) must attain an (b) (4) in a (b) (4)
(b) (4)

J. Methods of Attenuation:

N/A

III. HARVEST:

A. Handling and Preparation of Cultures and Media:

1. Production cultures are examined as described in II.I.
2. Upon reaching an (b) (4) is
(b) (4) and (b) (4)
3. Following (b) (4), the harvest is concentrated and purified as described in IV.C.
and stored (b) (4).

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III. B. Minimum and Maximum Time from Inoculation to Harvest:

The minimum and maximum time from inoculation to harvest is (b) (4), respectively.

C. Technique of Harvesting and Purification:

Harvests are concentrated (b) (4) as described in IV.C.

D. Specifications of acceptable harvest material:

1. Satisfactory harvests shall be pure based upon microscopic assessment of a (b) (4) sample.
2. Harvests must have an (b) (4).

E. Disposition of Discarded Material:

All materials not satisfactory for use shall be disposed in accordance with VSM 800.56.

IV. PREPARATION OF THE PRODUCT

A. Method of inactivation:

The harvest is inactivated by (b) (4)

B. Composition, Proportions, and Method of Addition of Preservatives, Adjuvants, or Stabilizers:

(b) (4)

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IV. B. 2. [REDACTED]

3. Although [REDACTED] is used during the [REDACTED] and also in the [REDACTED]
[REDACTED]; therefore, [REDACTED]
is not mentioned as a [REDACTED] in this section. The [REDACTED] out of
the product during the [REDACTED], which includes (b) (4)

(b) (4)

(b) (4)

C. Method and Degree:

1. [REDACTED]:

(b) (4)

a. 1) For cultures [REDACTED]
[REDACTED]
[REDACTED] (b) (4)
[REDACTED]

2) For cu (b) (4)

(b) (4)

Following [REDACTED] (b) (4)

is stored at [REDACTED]

2. [REDACTED]

a. The [REDACTED] from satisfactory harvests [REDACTED] is resuspended in [REDACTED]

b. Using [REDACTED], [REDACTED] with the
[REDACTED] at a [REDACTED]
[REDACTED] t with the [REDACTED]

(b)(6)

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(b) (4)

IV. C. 2. c.

[Redacted]

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spacing

3. [Redacted]:

(b) (4)

a. [Redacted] mM.

b. [Redacted]

[Redacted] (b) (4)

4. [Redacted]:

[Redacted] (b) (4)

✓ added
subsections
1) →

a. 1)

2) For cultures [Redacted]

b. [Redacted] (b)

5. [Redacted]

(b) (4)

a. [Redacted] (b) (4)

b. The [Redacted] can be [Redacted] up to [Redacted].

c. The resulting [Redacted] on a [Redacted].

✓ added
(d) }

(b)(6) [Redacted]
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d. The [Redacted]

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IV. C. 6. (b) (4) :

a. (b) (4)
[Redacted]

b. (b) (4)
[Redacted]

c. (b) (4)
[Redacted]

d. (b) (4)
[Redacted]

7. (b) (4) :

(b) (4)
[Redacted]

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IV. C. 8. Testing (b) (4) (Section IV.C.7.):

a. Purity:

1) (b) (4) (Section IV.C.7.) shall be tested for the

(b) (4)
[Redacted]
[Redacted]
[Redacted]
[Redacted]:

a) (b) (4)
[Redacted]
[Redacted]

b) (b) (4)
[Redacted]
[Redacted]

c) (b) (4)
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]

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IV. C. 8. a. 2)

[REDACTED] (Section IV.C.7.) shall be tested for the
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]).

a) [REDACTED] shall contain a
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

b) Test interpretation is described for final product serials in V.A.2.

3) [REDACTED] (Section IV.C.7.) shall be evaluated for e [REDACTED]
levels by the [REDACTED]
[REDACTED]
[REDACTED]:

a) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

b) Test interpretation is described for final product serials in V.A.3.

(b)(6)
[REDACTED]
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IV. C. 8. a. 4) Each (b) (4) (Section IV.C.7.) shall be tested for sterility and must be satisfactory in accordance with 9 CFR 113.26, (b) (4) is used in (b) (4) Fungal testing (b) (4) and bacterial testing at (b) (4)

b. Identity:

(b) (4) (Section IV.C.7.) shall be tested for identity (b) (4)

(b) (4) *char from*

was "9" → 1)

If the (b) (4) is determined to be (b) (4) according to (b) (4) shall be considered satisfactory.

*was party → 2)
"3" 10*

(b) (4) for the (b) (4), then the (b) (4) shall be determined to be (b) (4). If the (b) (4) is deemed (b) (4) y based upon the (b) (4)

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IV. C. 8. c. Quantity:

1)

[REDACTED]

2)

[REDACTED] the

[REDACTED]

[REDACTED]

(b)(6)

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IV. D. Procedures for Standardization of the Product:

1. [REDACTED]

2. The [REDACTED] is adjusted within a range [REDACTED], if required.

E. Assembly of a Serial:

1. One or more lots [REDACTED] (Section IV.C.7.) may be used to assemble a serial.

a. The [REDACTED]

b. The code [REDACTED] filled.

c. Example:

(b) (4)

(b) (4)

[REDACTED]

2. The [REDACTED]

(b)(6)

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IV. E. 3. [REDACTED]

F. Volume of Fill and Type of Container Used:

1. The volume final bulk mixture is filled [REDACTED] ml in a type 1 glass container.
2. Containers and closures are described in S.O. #4 and #2, respectively.

G. Method and Technique of Filling and Sealing Final Containers: [REDACTED] (b) (6)

1. The final bulk product is agitated throughout the filling process [REDACTED]
2. The mixture is aseptically filled into sterilized vials and sterile stoppers are applied to each vial.
3. The vials are then capped with aluminum seals.

H. Desiccation and Moisture Control:

N/A.

I. Amount of Antigenic Material Per Dose in the Final Container:

One dose of vaccine consists of [REDACTED] containing [REDACTED]
[REDACTED] by the methods described in Part V.C.

(b)(6)
[REDACTED]

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V. TESTING

A. Purity:

1. Each (b) (4) product is tested for sterility and must be satisfactory in accordance with 9 CFR 113.26. Fungal testing (b) (4) shall use (b) (4). Bacterial testing (b) (4) [redacted] APHIS on 21 August 2006.] - added ✓

2. Each (b) (4) shall be tested for (b) (4) (b) (4) against (b) (4) [redacted]

a. [redacted] (b) (4) (b) (4) (4) [redacted]

b. If (b) (4) is determined to (b) (4) the (b) (4) (b) (4) [redacted] ry.

3. Each (b) (4) shall be evaluated (b) (4) by the (b) (4) [redacted] Test interpretation shall be as follows:

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(b) (4)

V. A. 3. a.

[Redacted] shall contain [Redacted]

[Redacted] (b) (4)

b.

[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]

(b) (4)

B. Safety:

Each [Redacted] shall be tested for safety in mice using the intraperitoneal route and must be satisfactory in accordance with 9 CFR 113.33(b).

(b) (4)

C. Potency:

The [Redacted] was conducted by Merial, Inc., License No. 298, using [Redacted] and was approved by APHIS on October 26, 2009.
added per p + i ✓

[Redacted]
[Redacted]

1.

[Redacted]
[Redacted]
[Redacted]

(b)(6)



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V. C. 1. a. Criteria for [REDACTED]

(b)

1) The [REDACTED] for the [REDACTED]

[REDACTED]

2) The [REDACTED]

[REDACTED]

3) The [REDACTED] containing the [REDACTED] must [REDACTED]

[REDACTED]

4) If the [REDACTED] reported for a [REDACTED]

[REDACTED]

5) If the [REDACTED] reported for a [REDACTED]

[REDACTED]

(b)(6)

[REDACTED]

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V. C. 1. b. For a [REDACTED]
[REDACTED] If the s [REDACTED] is determined to be [REDACTED]
[REDACTED]. If [REDACTED] of the
[REDACTED] [REDACTED] shall be considered [REDACTED]. If
[REDACTED], then the [REDACTED] shall
be determined to be unsatisfactory. If [REDACTED]

2. Serials shall be [REDACTED]
[REDACTED]
[REDACTED]: [REDACTED]

a. Criteria for a Valid Assay: [REDACTED]

[REDACTED]

b. (b)(4) [REDACTED]

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Deleted (b)(4) 2/06 ✓

V. C.

(b) (4)

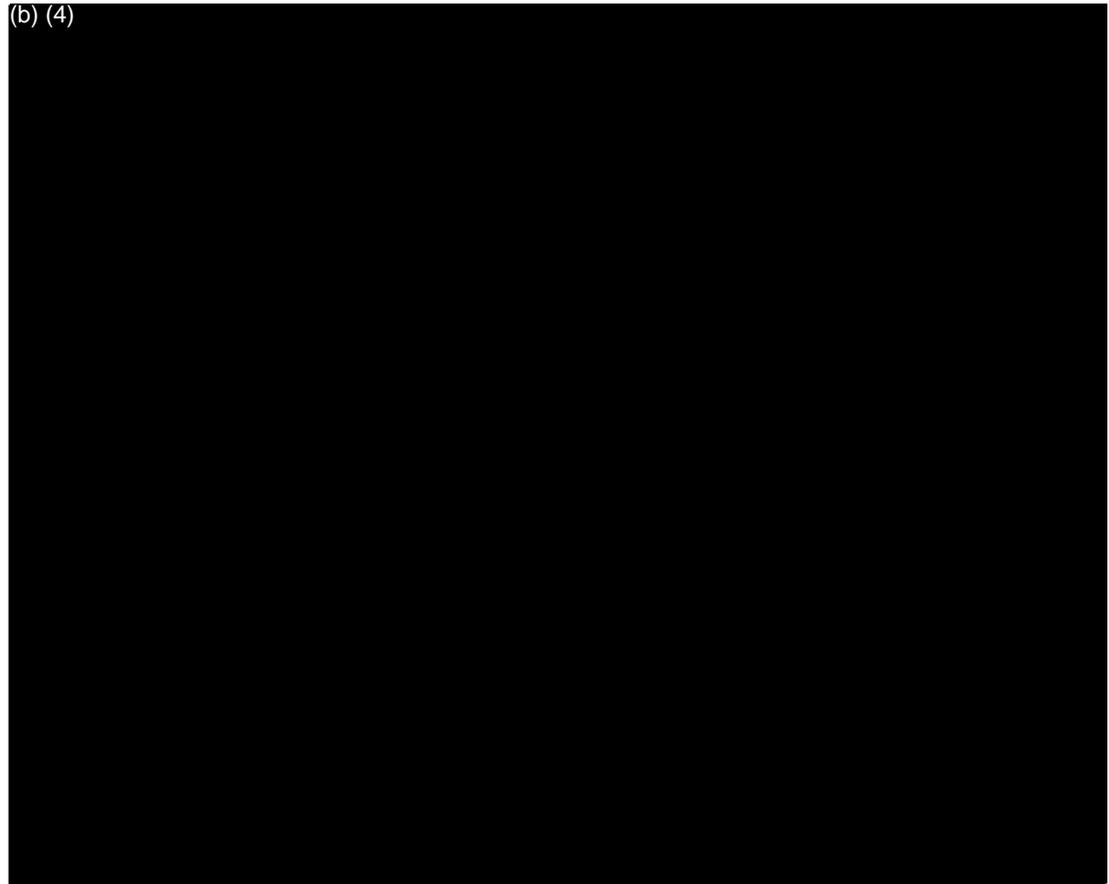


3. (b) (4)

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(b) (4) | a:

(b) (4)



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V. C. 4.

[REDACTED]

a. Criteria for a [REDACTED]:

[REDACTED]

b. [REDACTED]

c. [REDACTED]

(b)(6)

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4/17/07

V. C. 5.

added

(b) (4)
[Redacted]

a) (b) (4)
[Redacted]

b) (b) (4)
[Redacted]

c) (b) (4)
[Redacted]

D. Moisture:

N/A

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V. E. Other Tests:

Serials of completed bulk product or final container product shall be tested [REDACTED] For a [REDACTED], [REDACTED] shall be in the [REDACTED]

VI. POST PREPARATORY STEPS

A. Form and Size of Final Containers in Which the Product is to be Distributed:

1. The product is marketed in 4 x 1-dose packages, in single dose individual vials.
2. For the purpose of export, the product may be shipped unlabeled in accordance with 9 CFR 112.8(c).
3. The *"Canine"* VET JET[®] Transdermal Vaccination System *✓ "Device needle-free injection system"* manufactured by Bioject Medical Technologies, Bedminster, New Jersey, will be used for injection of the vaccine.

B. Collection, Storage, and Submission of Representative Samples:

1. Representative final container samples will be collected for quality control testing and reserve.
2. Samples in final containers for USDA-APHIS will be taken in accordance with 9 CFR 113.3 by an authorized firm sampler.

C. Expiration Date of the Product:

The expiration date is 24 months after the date of initiation of the first potency test, which will be confirmed in accordance with 9 CFR 114.13.

(b)(6)
[REDACTED]

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*UC Jg
#6-21-10
#6MS
6/22/10*

VI. D. Use, Dosage, and Route of Administration for Each Animal Species:

1. INDICATIONS: *from "is indicated for" per p+i*
The vaccine aids in extending survival times of dogs with stage II or stage III oral melanoma and for which local disease control has been achieved (negative local lymph nodes or positive lymph nodes that were surgically removed or irradiated).
2. DOSAGE: The vaccine is packaged in a box containing four single dose vials. This package of four vials is sufficient for the initial series of vaccinations required to treat one dog. The vaccine is administered in a 0.4 mL dose volume using the *from "Canine"* → *"Device" ✓* VET JET® Transdermal Vaccination System. Refer to the device package insert for instructions on vaccinating with the device. The site of injection for all size dogs is into the muscle of the medial thigh just caudal to the femur. Initial treatment requires administration of four doses of vaccine at two week intervals. A booster dose should be administered at six month intervals.
3. SAFETY: A transient, low-grade fever may be observed in some dogs. Transdermal injection has been associated with injection site pain, swelling, and bruising. Please see device label for complete information.
4. PRECAUTIONS: There are no known contraindications for the use of this product in dogs with oral melanoma. Store at 2 - 7°C (35 - 45°F). Do not freeze. Use entire contents when first opened. In rare instances, administration of vaccines may cause lethargy, fever, and inflammatory or hypersensitivity types of reactions. Treatment may include antihistamines, anti-inflammatories, and/or epinephrine.



*giz
6-21*

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VI. E. Statement of Confidentiality:

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Restricted Item	Page	Comment
I.	1 - 3	Source of microorganism is important to product efficacy.
II.	3 - 7	Identification and propagation techniques are important to product efficacy.
III.	7 - 8	Harvesting methods are important to product efficacy.
IV.	8 - 17	Production preparation and formulation are essential to product efficacy.
V.	18 - ²⁵ <i>Chp</i>	Testing standards are important to product efficacy.



#6
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RL
8-25-06

Est 298
S.O. # 2

BRA-RG-116

Version *5 Chg*

SPECIAL OUTLINE NO. 2 ✓

CLOSURES ✓

MERIAL, INC. ✓

115 TRANSTECH DRIVE ✓

ATHENS, GEORGIA 30601 ✓

ESTABLISHMENT LICENSE NO. 298 ✓

DATE: 07 NOVEMBER 2008 ✓

SUPERSEDES: 25 JUNE 2007 ✓

COMPLETE REVISION ✓

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Merial, Inc. License No. 298 Athens, Georgia	SPECIAL OUTLINE NO. 2 ✓ CLOSURES ✓	BRA-RG-116 Version 5
--	---------------------------------------	-------------------------

Page 1

Date: 07 November 2008 ✓
Supersedes: Complete Revision ✓

1.0 FORMULATION:

1.1 Fluted or plug stoppers are made of butyl, nitril, or natural rubber.

1.2 Stoppers are purchased from (b) (4) ^{added ✓} or equivalent source.
The diameters of the stoppers are (b) (4) for the (b) (4).

2.0 PREPARATION:

2.1 The stoppers may be (b) (4)

2.2 Stoppers are packaged in 4 L containers and sealed with steam permeable paper for sterilization. Alternatively, stoppers may be sterilized in autoclavable bags.

3.0 STERILIZATION:

Stoppers are sterilized (b) (4) accordance with 9 CFR 109.1(a).

4.0 TESTING:

N/A.

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5.0 STORAGE:

Stoppers may be [REDACTED]

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(b)(6)
[REDACTED]

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gg
12/29/08
#6MS
11/5/09

Est. 298
S.O. # 4

BRA-RG-118

Version 6 *dy*

SPECIAL OUTLINE NO. 4 ✓

FINAL CONTAINERS (GLASS) ✓

MERIAL, INC. ✓

115 TRANSTECH DRIVE ✓
ATHENS, GEORGIA 30601 ✓

PHONE (706) 548-9292 ✓

(b) (4) [REDACTED]

ESTABLISHMENT LICENSE NO. 298 ✓

DATE: 03 JUNE 2009 ✓

SUPERSEDES: 19 MARCH 2009 ✓

COMPLETE REVISION ✓

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Merial, Inc. License No. 298 Athens, Georgia ✓	SPECIAL OUTLINE NO. 4 ✓ FINAL CONTAINERS (GLASS) ✓	BRA-RG-118 ✓ Version 6 ✓ <i>Chg</i>
--	---	---

Page 1

Date: 03 June 2009 ✓
Supersedes: Complete Revision ✓

1.0 FORMULATION:

All glass containers are of Type 1 Flint. (b) (4) vials have a (b) (4) opening and containers over (b) (4) capacity have a (b) (4) opening. Glass containers for "Export Only" products may contain up to (b) (4)

2.0 PREPARATION:

Glass vials are received as a "clean pack" and are trayed in stainless steel or aluminum pans for sterilization (b) (4)

3.0 STERILIZATION:

Glass vials are sterilized in accordance with 9 CFR 109 (b) (4)

(b) (4)
(b) (4)
(b) (4) had crossed (b) (4)

4.0 TESTING:

N/A

5.0 STORAGE:

Sterile containers are kept for (b) (4)

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8/2
6/5/09
MS
#6 6/8/09
NC

Est. 299

(b) (4)

Est. 298

(b) (4)

BRA-RG-229

Version 1

SPECIAL OUTLINE (b) (4)

(b) (4)

MERIAL, INC.
115 TRANSTECH DRIVE
ATHENS, GEORGIA 30601

PHONE (706) 548-9292

(b) (4)

ESTABLISHMENT LICENSE NO. 298

DATE: 05 AUGUST 2005

SUPERSEDES: NEW

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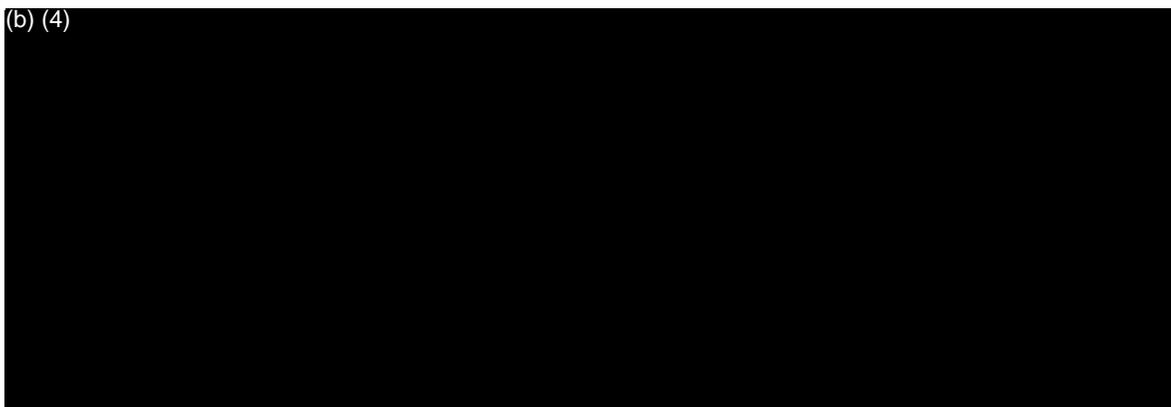
Merial, Inc. License No. 298 Athens, Georgia	SPECIAL OUTLINE NO. (b) (4) (b) (4)	BRA-RG-229 Version 1
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Page 1

Date: 05 August 2005
Supersedes: New

1.0 FORMULATION:

(b) (4)



2.0 PREPARATION:

2.1 Measure (b) (4)

2.2 (b) (4)

2.3 Adjust the (b) (4)

2.4 (b) (4)

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3.0 STERILIZATION:

Sterilize the [REDACTED].

4.0 TESTING:

N/A

5.0 STORAGE:

The [REDACTED]

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(b)(6)
[REDACTED]

Quality Assurance

8-12-05
#6
BT
NC

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298

(b) (4)

BRA-RG-238 ✓

Version 2 chg

SPECIAL OUTLINE NO. (b) (4)

(b) (4)

MERIAL, INC.
115 TRANSTECH DRIVE
ATHENS, GEORGIA 30601

PHONE (706) 548-9292
(b) (4)

ESTABLISHMENT LICENSE NO. 298

DATE: 28 AUGUST 2009 ✓
SUPERSEDES: 05 AUGUST 2005 ✓
COMPLETE REVISION ✓

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(b) (4)

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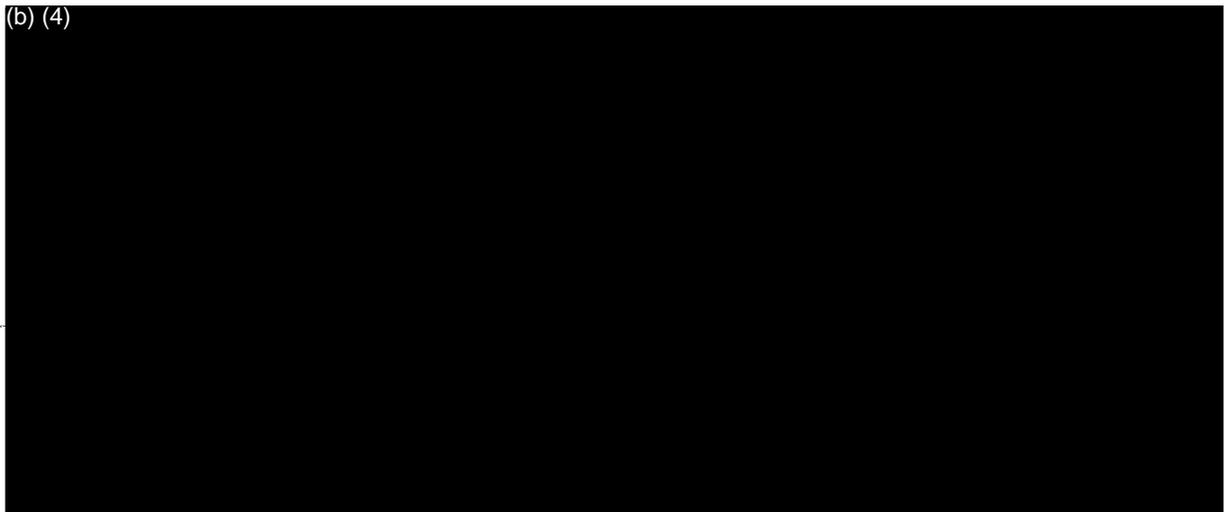
Page 1

Date: 28 August 2009 ✓
Supersedes: Complete Revision ✓

1.0 FORMULATION:

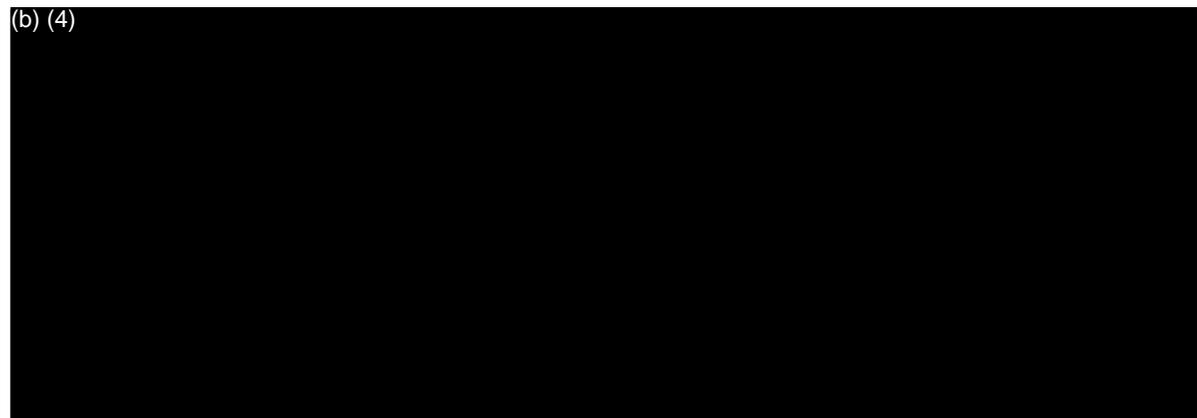
(b) (4)

✓ added -



2.0 PREPARATION:

(b) (4)



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3.0 STERILIZATION:

The [REDACTED] sterilized using a [REDACTED]

4.0 TESTING:

N/A

5.0 STORAGE:

The buffer may be stored at [REDACTED].

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(b)(6)
[REDACTED]

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gjs
10/5/09
#6 UC
MS
10/2/09

298
(b) (4)

BRA-RG-239 ✓

Version **2** ✓

SPECIAL OUTLINE **(b) (4)** ✓

[REDACTED] **(b) (4)** + " " ✓

MERIAL, INC. ✓
115 TRANSTECH DRIVE ✓
ATHENS, GEORGIA 30601 ✓

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DATE: 14 JANUARY 2009 ✓
SUPERSEDES: 17 APRIL 2006 ✓
Complete Revision ✓

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1.0 FORMULATION:

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

(b) (4)

2.0 PREPARATION:

- 2.1 Measure (b) (4)
- 2.2 (b) (4)
- 2.3 (b) (4)
- 2.4 (b) (4)

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3.0 STERILIZATION:

The [REDACTED].

4.0 TESTING:

N/A

5.0 STORAGE:

The [REDACTED].

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(b)(6)
[REDACTED]

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JW
2/5/09
#10MS
2/2/09

(b) (4)

✓ deleted 'BRA-RG-240'

Version ② "1"

SPECIAL OUTLINE (b) (4)

(b) (4)

MERIAL, INC.
115 TRANSTECH DRIVE
ATHENS, GEORGIA 30601

PHONE (706) 548-9292

(b) (4)

ESTABLISHMENT LICENSE NO. 298

DATE: 26 MARCH 2010

SUPERSEDES: 05 AUGUST 2005

Complete Revision

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deleted
"Meriel, Inc."
Athens, Georgia
from all
headers

License No. 298	SPECIAL OUTLINE (b) (4)	"BRR-RG-240" deleted Version 2 ver "1"
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Date: 26 March 2010
Supersedes: 05 August 2005
S/B Complete Revision

1.0 FORMULATION:

(b) (4)

2.0 PREPARATION:

2.1 Measure (b) (4)

2.2 (b) (4)

2.3 (b) (4)

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Date: 26 March 2010
Supersedes 05 August 2005
5/B Complete Revision

3.0 STERILIZATION:

[REDACTED]

4.0 TESTING:

N/A

5.0 STORAGE:

[REDACTED]

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5/3/10
6/5
5/24/10

Est. 298

(b) (4)

Est. 298

(b) (4)

BRA-RG-241

Version 1

SPECIAL OUTLINE NO. (b) (4)

(b) (4)

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Page 1

Date: 05 August 2005
Supersedes: New

1.0 FORMULATION:

(b) (4)

2.0 PREPARATION:

(b) (4)

(b) (4)

(b) (4)

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3.0 STERILIZATION:

The [REDACTED]

4.0 TESTING:

N/A

5.0 STORAGE:

The [REDACTED] may be stored [REDACTED].

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8-12-05

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BRA-RG-242

Version 1

SPECIAL OUTLINE

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ATHENS, GEORGIA 30601

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Merial, Inc. License No. 298 Athens, Georgia	SPECIAL OUTLINE (b) (4) (b) (4)	BRA-RG-242 Version 1
--	------------------------------------	-------------------------

Page 1

Date: 05 August 2005
Supersedes: New

1.0 FORMULATION:

(b) (4)

2.0 PREPARATION:

2.1 (b) (4)

2.2 (b) (4)

2.3 (b) (4)

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3.0 STERILIZATION:

The [REDACTED] sterilized [REDACTED].

4.0 TESTING:

N/A

5.0 STORAGE:

The [REDACTED] may be stored [REDACTED].

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#6
BMC NC
8-12-05

Est. 298
S.O. #63

Est. 298
(b) (4)

BRA-RG-243

Version 1

SPECIAL OUTLINE **(b) (4)**

(b) (4)

MERIAL, INC.
115 TRANSTECH DRIVE
ATHENS, GEORGIA 30601

PHONE (706) 548-9292

(b) (4)

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DATE: 05 AUGUST 2005

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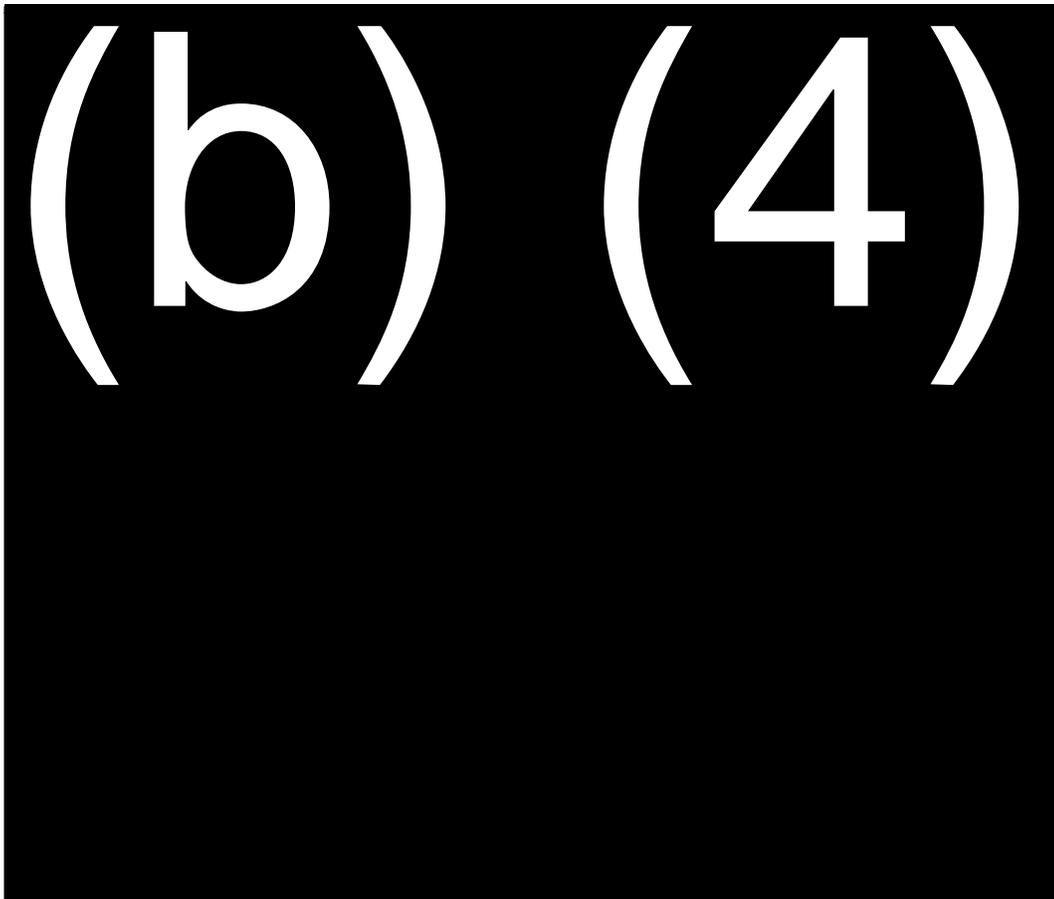
Merial, Inc. License No. 298 Athens, Georgia	SPECIAL OUTLINE (b) (4) (b) (4)	BRA-RG-243 Version 1
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Page 1

Date: 05 August 2005
Supersedes: New

1.0 (b) (4):

1.1 Formulation:



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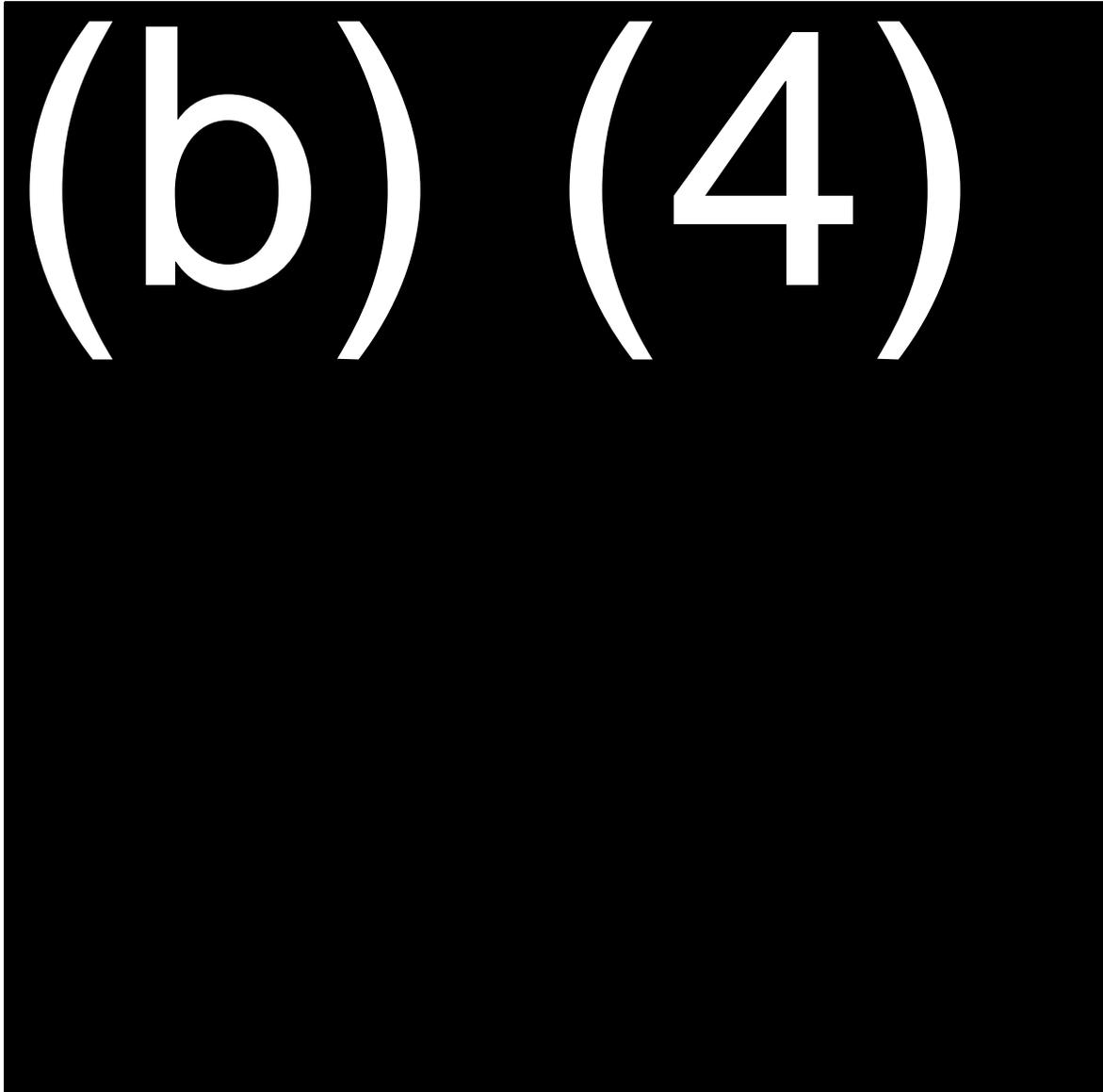
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1.2 Preparation:

1.2.1 The following (b) (4) prepared in the (b) (4) indicated. All may be prepared in advance.



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1.2.1 Continued

Prepare (b) (4) e. Add the (b) (4)
in order as above, to (b) (4)

1.2.2 (b) (4)

1.2.3 (b) (4) :

(b) (4)

1.3 Sterilization:

The (b) (4)

1.4 Testing:

N/A

1.5 Storage:

The (b) (4) may be stored at (b) (4)

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2.0 COMPLETE (b) (4)
PRODUCTION:

2.1 Formulation:

(b) (4)

2.2 Preparation:

2.2.1 Completely (b) (4)
[Redacted]

2.2.2 Once (b) (4)
[Redacted]

2.3 Sterilization:

Complete (b) (4) sterilized (b) (4)
[Redacted]

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2.4 Testing:

NA

2.5 Storage:

2.5.1 Complete (b) (4)

2.5.2 Complete (b) (4)

s.

3.0 COMPLETE (b) (4)

PRODUCTION:

3.1 Formulation:

(b) (4)

3.2 Preparation:

3.2.1 (b) (4) is added (b) (4)

3.2.2 (b) (4)

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3.3 Sterilization:

Complete [REDACTED] s sterilized by [REDACTED].

3.4 Testing:

(b) (4)

3.5.2 Complete [REDACTED] (b) (4)
[REDACTED].

4.0 [REDACTED]

4.1 Formulation:

[REDACTED]

* [REDACTED] or equivalent

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(b)(6)
[REDACTED]

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4.2 Preparation:

[REDACTED]

4.3 Sterilization:

[REDACTED]

4.4 Testing:

There is no testing performed [REDACTED].

4.5 Storage:

[REDACTED] may be stored at [REDACTED]

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B4
[REDACTED]

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JD
8-12-05

Ext 298

(b) (4)

Ext 298

(b) (4)

BRA-RG-244

Version 1

SPECIAL OUTLINE (b) (4)

(b) (4)

MERIAL, INC.
115 TRANSTECH DRIVE
ATHENS, GEORGIA 30601

PHONE (706) 548-9292

(b) (4)

ESTABLISHMENT LICENSE NO. 298

DATE: 05 AUGUST 2005

SUPERSEDES: NEW

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Merial, Inc. License No. 298 Athens, Georgia	SPECIAL OUTLINE (b) (4) (b) (4)	BRA-RG-244 Version 1
--	------------------------------------	-------------------------

Page 1

Date: 05 August 2005
Supersedes: New

1.0 FORMULATION:

<u>Ingredient</u>	<u>Grade</u>	<u>Amount / liter</u>
(b) (4)		
*(b) (4)	equivalent	

2.0 PREPARATION:

2.1 (b) (4) preparation:

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

(b) (4)

(b) (4)

2.2 (b) (4)

(b) (4)

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3.0 STERILIZATION:

3.1 The [REDACTED] is sterile [REDACTED]
[REDACTED]

3.2 [REDACTED] is sterilized [REDACTED]
[REDACTED]

4.0 TESTING:

[REDACTED]

5.0 STORAGE:

The [REDACTED] be stored at [REDACTED].

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(b)(6)
[REDACTED]

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8-12-05

(b) (4)

Est. 298

BRA-RG-231 ✓

Version 1 ✓

SPECIAL OUTLINE (b) (4) ✓

(b) (4) ✓

MERIAL, INC.
115 TRANSTECH DRIVE
ATHENS, GEORGIA 30601 ✓

ESTABLISHMENT LICENSE NO. 298 ✓

DATE: 19 DECEMBER 2006 ✓
SUPERSEDES: 10 MAY 2006 ✓
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1.0 MATERIALS AND FORMULAS:

1.1 (b) (4)

(b) (4)

1.2 (b) (4)

(b) (4)

added ✓

(b) (4)

(b) (4)

1.3 (b) (4)

(b) (4)

1.4 (b) (4)

(b) (4)

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1.5 (b) (4)

(b) (4)

2.0 PROCEDURE FOR (b) (4):

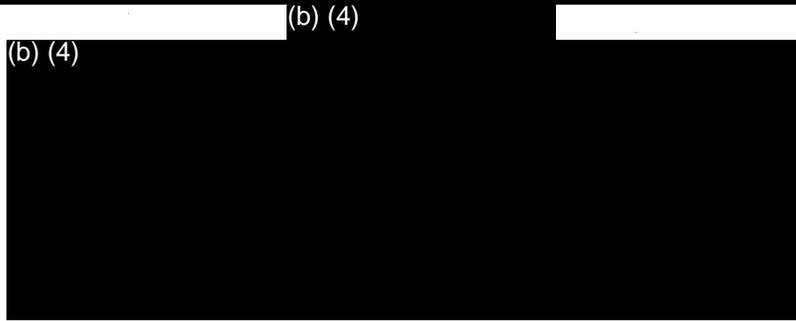
2.1 Prepare Cuvettes for Absorbance Measurement:

(b) (4)



chg

(b) (4)



2.1.4 (b) (4)



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2.1.5 Measure (b) (4) of (b) (4) as described in 2.2.

2.2 Measuring Absorbance:

2.2.1 (b) (4) [Redacted]

2.1.2 (b) (4) [Redacted]

2.3 Data Calculations:

2.3.1 (b) (4) [Redacted]

2.3.2 (b) (4) [Redacted]

2.3.3 (b) (4) [Redacted]

2.3.4 (b) (4) [Redacted]

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2.3.5 [REDACTED] is determined for [REDACTED]
[REDACTED]
[REDACTED]

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(b)(6)
[REDACTED]

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(b) (4)

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Version 1 ✓

SPECIAL OUTLINE (b) (4) ✓

(b) (4)

MERIAL, INC.

115 TRANSTECH DRIVE
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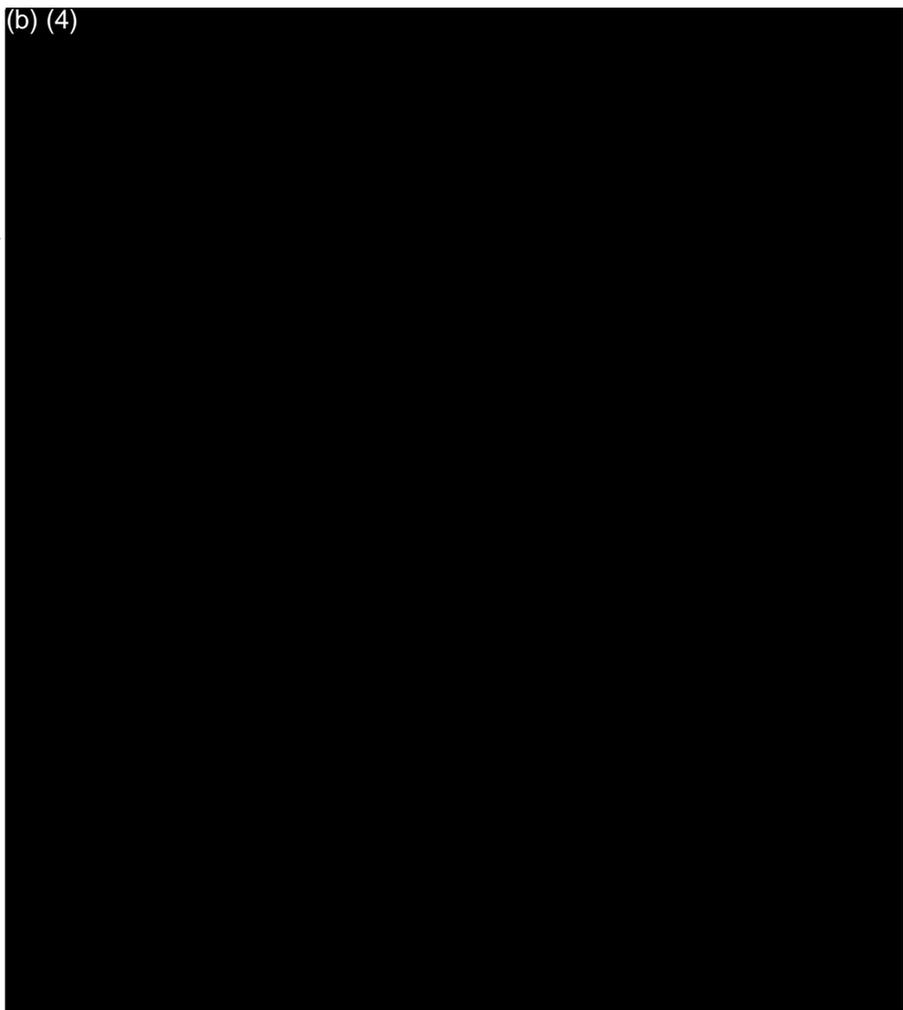
Merial, Inc. License No. 298 Athens, Georgia	SPECIAL OUTLINE (b) (4) (b) (4) (b) (4)	BRA-RG-233 Version 1
--	---	-------------------------

Page 1

Date: 19 December 2006
Supersedes: Complete Revision

1.0 MATERIALS AND FORMULATIONS:

(b) (4)



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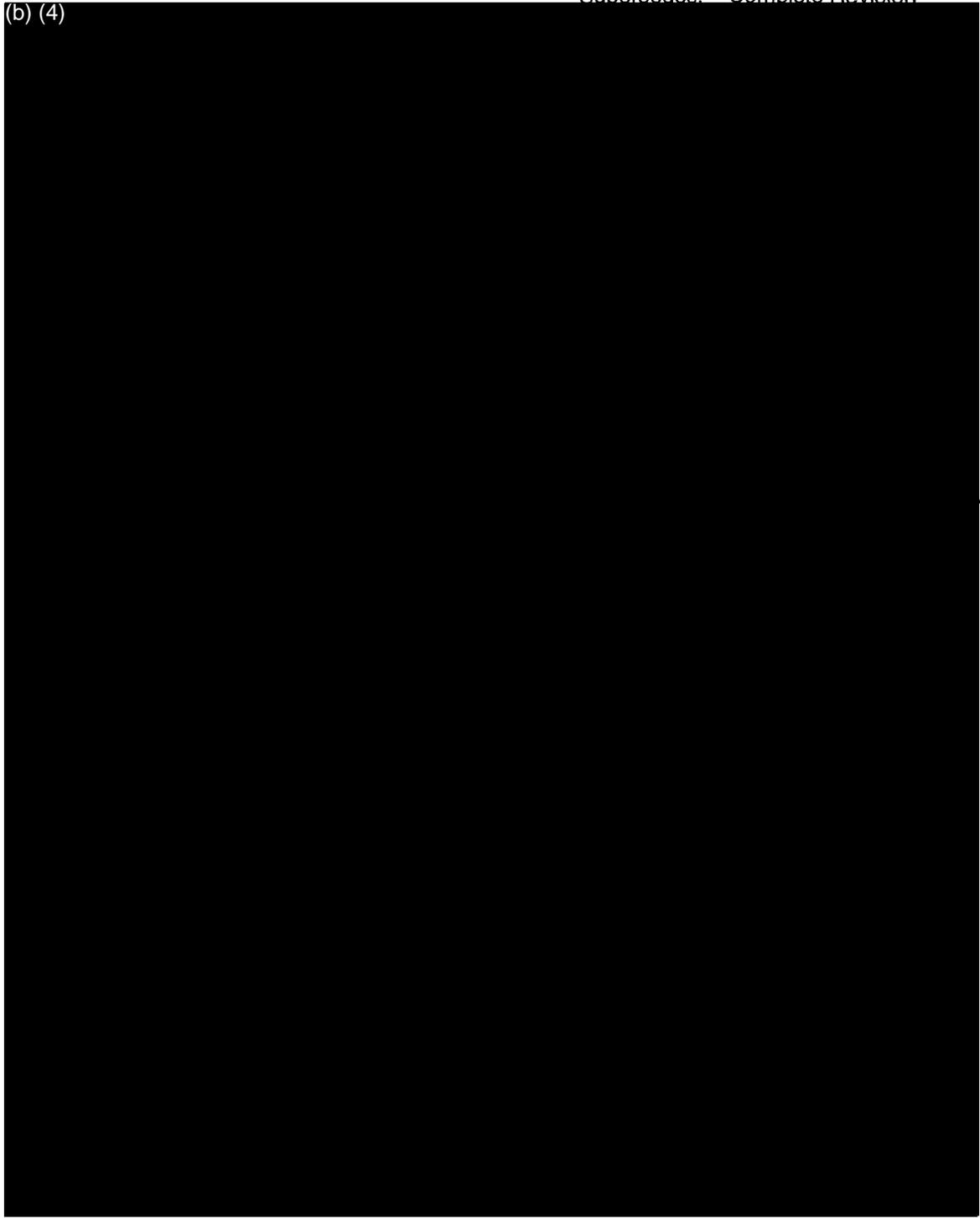
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(b) (4)



1.11

1.12

1.13

1.14

✓ 1.15

1.16

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1.17 (b) (4):

(b) (4)

Reagent provided to CVB-PEL upon request.

1.18 (b) (4)

(b) (4) Reagent provided to CVB upon request.

1.19 (b) (4)

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

1.20 (b) (4)

(b) (4)
(b) (4)
(b) (4) or equivalent.

1.21 (b) (4) or equivalent:

(b) (4)

1.22 (b) (4)

(b) (4) or equivalent.

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1.23 [REDACTED], or
equivalent. (b) (4)

1.24 [REDACTED]:

(b) (4)
[REDACTED]

Store [REDACTED]
Expiration dating [REDACTED] is determined by the expiration date of the
[REDACTED], which is [REDACTED].

1.25 [REDACTED]
[REDACTED]

1.26 [REDACTED]
[REDACTED]

(b)(6)
[REDACTED]

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89
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82969M DEC 15 2009

2.0 PROCEDURE (b) (4) :

2.1 Preparation (b) (4)

2.1.1 Prepare (b) (4) Section 1.24.

2.1.2 [Redacted]

2.2 (b) (4) :

Examine (b) (4)
[Redacted]

2.3 Prepare (b) (4) :

(b) (4)
[Redacted]

2.3.1 Add (b) (4)
[Redacted]

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2.3.2 (b) (4) [Redacted]

2.3.3 (b) (4) (b) (4) [Redacted]

(b) (4) [Redacted]

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(b) (4) [Redacted]

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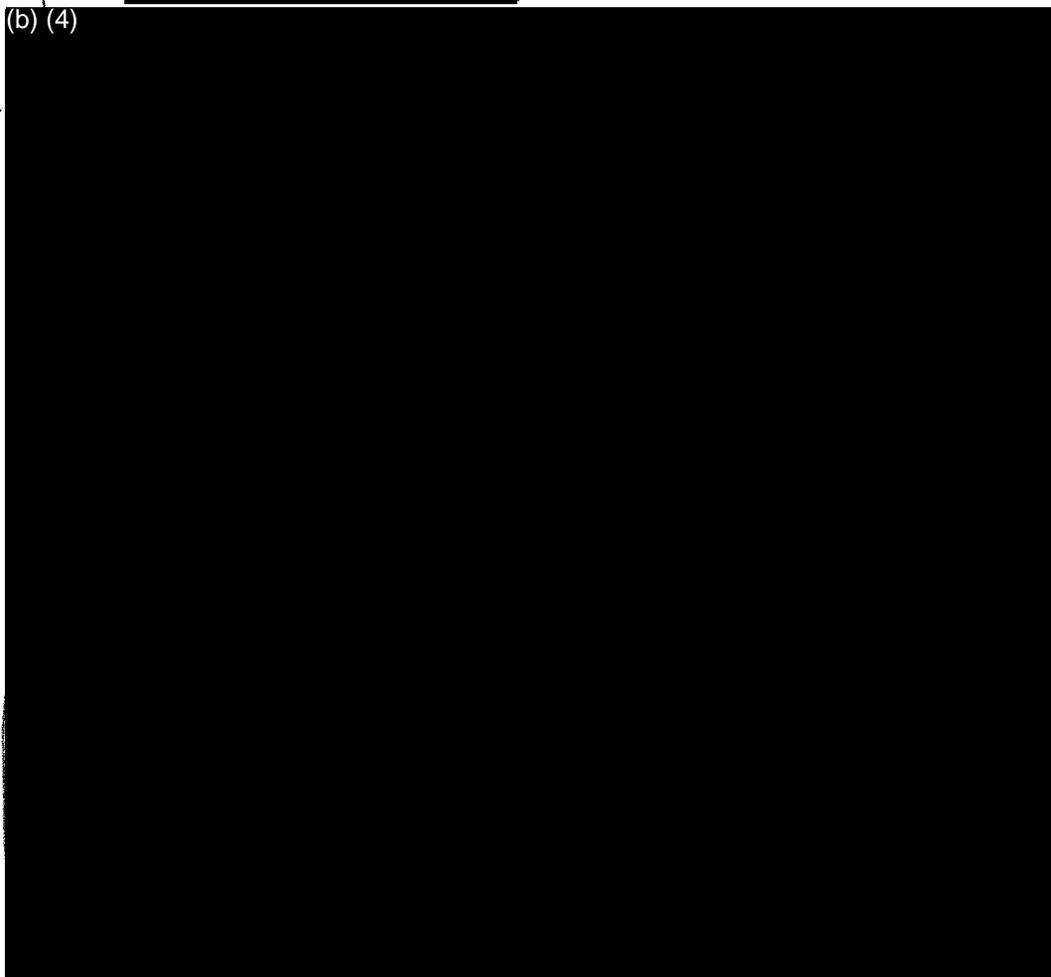
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2.3.4 (b) (4). For example, prepare a
(b) (4)
(b) (4)

2.3.5 (b) (4):
(b) (4)
(b) (4)
(b) (4)

added

(b) (4)



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(b) (4)

2.4.1 Prepare (b) (4) in Section 1.25.

2.4.2 Add (b) (4) (b) (4) (b) (4) (b) (4) 3" ✓

2.4.3 Add (b) (4) (b) (4)

2.4.4 Add (b) (4) (b) (4) (b) (4) (b) (4)

2.4.5 For example, (b) (4) could follow the following scheme:

2.4.5.1 Add (b) (4)

(b) (4)

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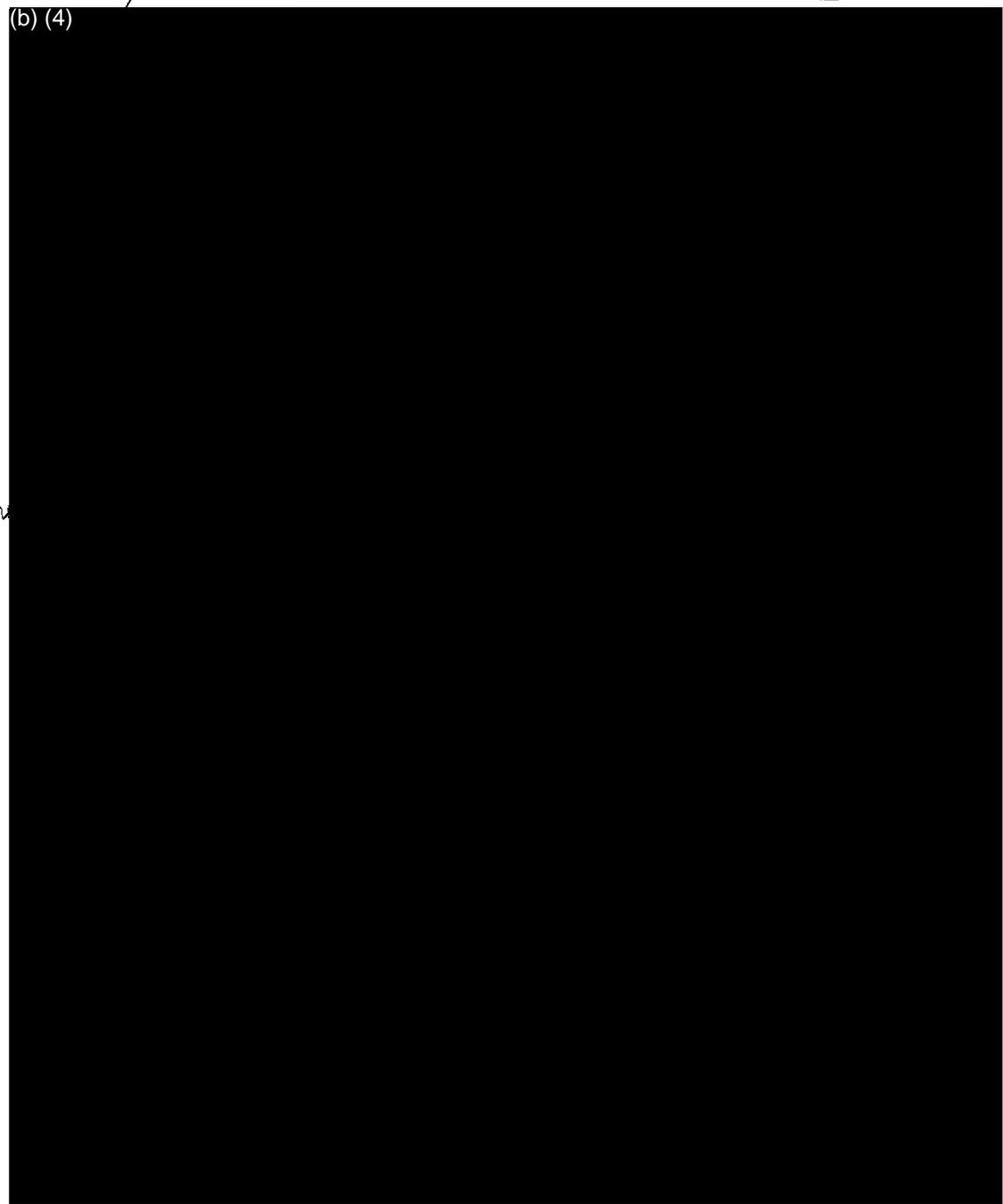
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(b) (4)
(b) (4)

2.4.5.4 [REDACTED]

(b) (4)



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[Redacted]

2.4.6 Incubate the [Redacted]

2.5 Add [Redacted]

2.5.1 Transfer [Redacted]
[Redacted] [Redacted] [Redacted] [Redacted]
[Redacted]

2.5.2 [Redacted] [Redacted]
[Redacted] [Redacted]
[Redacted]

2.5.3 [Redacted] (b) (4)
[Redacted]
[Redacted]
[Redacted]
[Redacted]

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[Large Redacted Block]

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2.6 Incubate [redacted]

2.7 [redacted] plate. (b) (4)

2.8 Prepare [redacted] Section 1.26.

2.9 [redacted]
[redacted] (b) (4)
[redacted]
[redacted] (b) (4)

2.10 [redacted]

2.10.1 [redacted]
[redacted]

2.10.2 [redacted] (b) (4)

2.10.3 [redacted]
[redacted]

2.10.4 [redacted]

2.11 Examine [redacted]

2.11.1 [redacted]

Janice Coon

Janice Coon
Quality Operations

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1/7/10
#605
MS
1/11/10

2.11.2 Record [REDACTED]

2.11.3 Record [REDACTED]

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Red
1-25-07
#6
MS, 1/26/07

(b) (4)

Est. 298

BRA-RG-234 ✓

Version 1 ✓

(b) (4) SPECIAL OUTLINE (b) (4)

MERIAL, INC. ✓
115 TRANSTECH DRIVE ✓
ATHENS, GEORGIA 30601

ESTABLISHMENT LICENSE NO. 298 ✓

DATE: 19 DECEMBER 2006 ✓
SUPERSEDES: 17 APRIL 2006 ✓
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1.0 MATERIALS AND FORMULAS:

1.1 (b) (4) :

(b) (4)
, or equivalent, (b) (4)

(b) (4)

1.2 (b) (4)
(b) (4)

1.3 (b) (4)

1.4 (b) (4) or equivalent (b) (4)
, or equivalent.

1.5 (b) (4), or equivalent.

1.6 (b) (4)

1.7 (b) (4)
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(b) (4)

1.8 [Redacted]
[Redacted]
[Redacted]

1.9 [Redacted]
[Redacted] (b) (4)
[Redacted]
[Redacted], or equivalent [Redacted]

1.10 [Redacted]
[Redacted], or equivalent.

(b) (4)

1.11 Plasmid DNA Mass Standard:

[Redacted]
[Redacted] Reagent will be provided to the CVB-PEL upon request.

1.12 [Redacted]:

[Redacted]
[Redacted]

1.13 [Redacted]
[Redacted]
[Redacted]

1.14 [Redacted] or
equivalent.

(b)(6)
[Redacted]

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8/28
1/7/10 NC
#MS
1/11/10

2.0 PROCEDURE:

2.1 Prepare (b) (4) :

Prepare (b) (4)
[Redacted]

2.2 Preparation of (b) (4)
[Redacted]

2.2.1 (b) (4)

Assemble (b) (4)
[Redacted]

2.2.2 (b) (4) :

Remove the (b) (4) from the (b) (4) and (b) (4)
[Redacted]. Place (b) (4) in the (b) (4) cell. Cover (b) (4) with (b) (4) to
the (b) (4) typically located on (b) (4) of the (b) (4) [Redacted]. Remove (b) (4)
from (b) (4)

2.3 Add (b) (4) [Redacted] (b) (4) of this
(b) (4)) will result in (b) (4) [Redacted].

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2.4 (b) (4)

2.4.1 Using (b) (4) _____
_____/μl.

2.4.2 Add (b) (4) _____
_____ well.

2.5 (b) (4) _____:

(b) (4) _____ (b) (4) _____ wells by loading
_____ μl of (b) (4) _____

2.5.2 Attach (b) (4) _____ ensuring that (b) (4) _____

2.5.3 Run the _____ (b) (4) _____
added *added*

2.5.4 Remove (b) (4) _____ and (b) (4) _____ (b) (4) _____
_____ by _____ (b) (4) _____
(b) (4) _____ gel. Pour (b) (4) _____ over the
gel and stain for 25 - 35 minutes. [The CVB retains the right (b) (4) _____
(b) (4) _____ in (b) (4) _____ so (b) (4) _____

2.6 Analyze the (b) (4) _____

2.6.1 Capture (b) (4) _____ using a (b) (4) _____, or equivalent.

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2.6.2 (b) (4)
[Redacted]
[Redacted]
[Redacted] (b) (4)
[Redacted] (b) (4)

2.6.3 (b) (4)
[Redacted]
[Redacted]
[Redacted] nt. Follow instructions provided in
the (b) (4) for (b) (4)

2.6.4 (b) (4)
[Redacted]
[Redacted] e. Follow instructions provided in (b) (4)
[Redacted] (b) (4)

2.6.5 (b) (4)
[Redacted]
[Redacted] (b) (4)

2.6.6 (b) (4)
[Redacted]
[Redacted]
[Redacted]
[Redacted]

2.6.7 Record the (b) (4)

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2.6.8 (b) (4) [REDACTED]
(b) (4) [REDACTED]
(b) (4) [REDACTED]

2.6.9 Analyze (b) (4) [REDACTED]
(b) (4) [REDACTED]
(b) (4) [REDACTED]

2.6.10 Record the (b) (4) [REDACTED]

2.6.11 (b) (4) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

2.6.12 Analyze (b) (4) [REDACTED]
[REDACTED] (b) (4) [REDACTED]
[REDACTED]

2.6.13 Record (b) (4) [REDACTED]
[REDACTED]

2.7 (b) (4) [REDACTED]

2.8 (b) (4) [REDACTED]

2.8.1 (b) (4) [REDACTED]
[REDACTED]

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(b)(6)
[REDACTED]

Quality Operations

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9-4-10
#6MS
9/8/10

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Est. 298

(b) (4)

BRA-RG-235

Version 1

SPECIAL OUTLINE (b) (4)

(b) (4)

MERIAL, INC.
115 TRANSTECH DRIVE
ATHENS, GEORGIA 30601

ESTABLISHMENT LICENSE NO. 298

DATE: 19 DECEMBER 2006
SUPERSEDES: 17 APRIL 2006
COMPLETE REVISION

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Merial, Inc. License No. 298 Athens, Georgia	SPECIAL OUTLINE (b) (4) (b) (4) (b) (4) (b) (4)	BRA-RG-235 Version 1
--	---	-------------------------

1.0 MATERIALS AND FORMULAS:

1.1 (b) (4) :

(b) (4)
(b) (4), or equivalent, (b) (4)
(b) (4)
(b) (4)

1.2 (b) (4)
(b) (4)

1.3 (b) (4) or equivalent.

1.4 (b) (4)
(b) (4)
(b) (4), or equivalent.

1.5 (b) (4) or equivalent.

1.6 Deionized water.

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1.7 [Redacted]
[Redacted] (b) (4)

1.8 [Redacted]
[Redacted] lane.

[Redacted] (b) (4)
1.9 [Redacted]
[Redacted] (b) (4)
[Redacted] or equivalent. [Redacted]
[Redacted]

1.10 [Redacted] (b) (4)

1.11 [Redacted], or
equivalent.

1.12 [Redacted]
[Redacted], or equivalent, prepared to manufacturer's
recommendations.

1.13 [Redacted] or
equivalent.

1.14 R [Redacted] or equivalent.

1.15 [Redacted], or
equivalent.

(b)(6)
[Redacted]

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2/7/10

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1.16 [REDACTED], or equivalent.

1.17 *deleted "Innitrogen" added*
[REDACTED]
[REDACTED]

1.18 [REDACTED] (b) (4)
[REDACTED], or equivalent.
[REDACTED]
[REDACTED]

2.0 PROCEDURE:

2.1 Prepare 1 [REDACTED]

Prepare [REDACTED]
[REDACTED]

2.2 Preparation [REDACTED]
[REDACTED].

2.2.1 Manual Preparation:

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

(b)(6)
[REDACTED]

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2.2.2 (b) (4) :

(b) (4)

2.3 Prepare

2.3.1

(b) (4) (4)

To prepare the (b) (4) add the following (b) (4)

2.3.3 Place (b) (4). Ensure the entire (b) (4).

2.3.4 Incubate the (b) (4).

2.3.5 Add 3 µl loading dye to each dilution.

2.4 Prepare (b) (4).

Add the following to (b) (4)

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2.5 (b) (4):

2.5.1 (b) (4)

2.5.2 Attach (b) (4) ensuring that (b) (4)

2.5.3 (b) (4) *added* *added*

2.5.4 (b) (4)

2.6 Analyze (b) (4):

2.6.1 Capture the (b) (4) using a (b) (4), or equivalent.

2.6.2 (b) (4) is only able (b) (4)
he (b) (4) than this are (b) (4) by
the system. Therefore, for those (b) (4) that are (b) (4)
kilobases according to (b) (4) (H), use the
(b) (4) (b) (4)

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2.6.3 [Redacted]
[Redacted]
[Redacted] (b) (4) (b) (4)

3.0 [Redacted]: (b) (4)

Report [Redacted]

4.0 VALIDITY CRITERIA:

4.1 [Redacted] be present in [Redacted]
[Redacted]
[Redacted]

4.2 [Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]

4.3 [Redacted] resulting from [Redacted] shall be [Redacted] or the
test will [Redacted].

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[Redacted]

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1/30/07

Est. 298

(b) (4)

BRA-RG-236

Version 1

SPECIAL OUTLINE (b) (4)

(b) (4)

MERIAL, INC.
115 TRANSTECH DRIVE
ATHENS, GEORGIA 30601

PHONE (706) 548-9292

(b) (4)

ESTABLISHMENT LICENSE NO. 298

DATE: 05 AUGUST 2005

SUPERSEDES: NEW

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Merial, Inc. License No. 298 Athens, Georgia	SPECIAL OUTLINE (b) (4) (b) (4) (b) (4) E(b) (4)	BRA-RG-236 Version 1
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1.0 MATERIALS AND FORMULATIONS:

1.1 (b) (4)

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

1.2 (b) (4)

(b) (4) or equivalent.

1.3 (b) (4):

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

1.4 (b) (4):

(b) (4), or equivalent, (b) (4)
(b) (4), or
equivalent.

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(b) (4)
Page 2

Date: 17 April 2006 ✓
Supersedes: 05 August 2005 ✓

1.5 [redacted]

[redacted] or equivalent
(b) (4)

1.6 [redacted]:

[redacted], or equivalent.

1.7 [redacted].

(b) (4)

1.8 [redacted]:

[redacted] or equivalent
(b) (4)

1.9 [redacted]

[redacted] Fisher Scientific, Hampton, New
(b) (4)
[redacted] or equivalent.

[redacted]
[redacted] or equivalent.

1.10 [redacted]
[redacted], or equivalent.

1.11 [redacted]:

[redacted]. Reagent will be provided to the
CVB-PEL upon request.

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1.12 (b) (4) :

(b) (4) . Reagent will be provided to the
CVB-PEL upon request.

1.13 (b) (4) :

(b) (4) . Reagent will be provided to the CVB-PEL
upon request.

1.14 (b) (4) :

The pDNA sample to be tested should have a pDNA concentration of 20 ng pDNA/ μ l.

1.15 (b) (4) dye:

(b) (4)
(b) (4) or equivalent, prepared to (b) (4)
(b) (4)

1.16 (b) (4) or
equivalent.

2.0 PROCEDURE FOR (b) (4) :

The (b) (4) to be tested by this procedure (b) (4)
(b) (4)
(b) (4)
(b) (4)
(b) (4) of this procedure (b) (4)
(b) (4)

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(b) (4)

(b) (4)

(b) (4)

2.1 Prepare 1 (b) (4) :

Prepare (b) (4) [redacted]
[redacted]

2.2 Preparation (b) (4) :

Use (b) (4) [redacted]
[redacted]

2.2.1 (b) (4) :

(b) (4) [redacted]
[redacted]
[redacted]
[redacted]

2.2.2 (b) (4)

Remove the (b) (4) (b) (4) [redacted]
[redacted]
[redacted] cell. Remove the comb
(b) (4) [redacted]

2.3 Preparing (b) (4) :

Add (b) (4) [redacted]

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2.4 [redacted] (b)(4) (b)(4)

2.4.1 Using [redacted], prepare [redacted] the following [redacted] / μ l.

2.4.2 Add 9 [redacted] (b)(4) (b)(4)

2.5 [redacted] (b)(4)

Add [redacted]

2.6 [redacted] (b)(4)

2.6.1 Add [redacted] of each of the [redacted] to [redacted].

2.6.2 Add [redacted] the sample [redacted].

2.6.3 Add [redacted] of the [redacted].

2.6.4 Add [redacted] of the [redacted].

2.7 [redacted]

R added ✓

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(b) (4)

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Date: 11 July 2008 ✓
 Supersedes: 03 August 2005 ✓

(b) (4)

2.8

Remove [redacted] from [redacted] cell and place in [redacted]
 [redacted]. Prepare an ethidium [redacted] [redacted]
 [redacted] [redacted] [redacted] [redacted] prepare enough [redacted] (b) (4)
 [redacted] Pour the [redacted] s.

added

[The CVB retains the right to include [redacted] (b) (4)
 [redacted]

(b) (4)

2.9 Analyze the [redacted]:

2.9.1 Capture the [redacted] using a [redacted] [redacted], or equivalent.

2.9.2 Using the [redacted], [redacted].

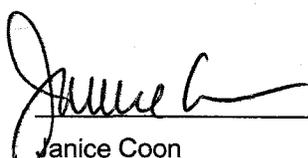
2.9.3 On the [redacted], identify [redacted]
 [redacted]

(b) (4)

2.9.4 On the [redacted], identify [redacted]
 [redacted] [redacted]
 [redacted]

2.9.5 Using the [redacted] examine, with [redacted]
 [redacted] d to those [redacted] in the [redacted] containing
 [redacted].

2.9.6 [redacted]
 [redacted]
 [redacted]
 [redacted]
 [redacted]
 [redacted]


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19-12-08 #6
MS 9/24/08

- 3.0 [REDACTED]: [REDACTED]
- 3.1 [REDACTED]
[REDACTED]
- 3.2 [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
- 3.3 [REDACTED]
[REDACTED]
[REDACTED]

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[REDACTED]

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Version 1

SPECIAL OUTLINE NO (b) (4)

(b) (4)

MERIAL, INC.
115 TRANSTECH DRIVE
ATHENS, GEORGIA 30601

PHONE (706) 548-9292

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ESTABLISHMENT LICENSE NO. 298

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- 1.6 (b) (4)
- 1.7 (b) (4)
- 1.8 (b) (4)
- 1.9 (b) (4)
- 1.10 (b) (4)
- 1.11 (b) (4)
- 1.12 (b) (4)
- 1.13 (b) (4)
- 2.0 PROCEDURE FOR DETERMINING (b) (4):
 - 2.1 Sample Storage:
 - 2.1.1 Samples being stored for (b) (4) may be kept at (b) (4) otherwise, samples are to be stored (b) (4).
 - 2.1.2 (b) (4) does not (b) (4); it may be kept at (b) (4).
 - 2.2 (b) (4) and (b) (4) preparation:
 - 2.2.1 Bring all (b) (4) and (b) (4).

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2.2.2 (b) (4) :

2.2.2.1 (b) (4)

2.2.2.2 Shake (b) (4)

2.2.2.3 Shake (b) (4)

2.2.2.4 Remove (b) (4)

2.3 Reader Set-up

2.3.1 Open the (b) (4)

2.3.2 Set the (b) (4) with the following (b) (4)

2.3.3 Configure a plate to contain (b) (4)

2.3.4 Set up a (b) (4) (b) (4) (b) (4)
Click the (b) (4) in the (b) (4) to have samples (b) (4)

2.3.5 Enter (b) (4)

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2.3.6 (b) (4).

2.4 Sample Dilutions:

2.4.1 Prepare (b) (4) using (b) (4) and (b) (4) for each (b) (4).

2.4.2 (b) (4)

2.4.3 (b) (4)

2.4.4 Continue (b) (4) - 2.4.3

2.5 Endotoxin Standard Dilutions:

2.5.1 After (b) (4) d has been (b) (4) s, dispense (b) (4). This is a (b) (4).

2.5.2 Using (b) (4), prepare (b) (4) containing the following (b) (4).

2.5.3 In a (b) (4) dispense (b) (4) water to be used as the (b) (4).

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2.6 (b) (4) Preparation:

2.6.1 (b) (4) . Dispense (b) (4) of the
(b) (4)

2.6.2 (b) (4)

2.6.3 When (b) (4) , incubate the (b) (4)
(b) (4)

2.6.4 Insert (b) (4) (b) (4)

2.6.5 (b) (4)

2.6.6 (b) (4)

2.7 (b) (4)

Allow (b) (4)
with the appropriate (b) (4)

2.8 (b) (4) :

2.8.1 (b) (4)

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2.8.2 [REDACTED]
dilution factor.

2.8.3 [REDACTED] in
[REDACTED]

3.0 VALIDITY REQUIREMENTS

3.1 The [REDACTED] must [REDACTED] the tes
[REDACTED]

3.2 The [REDACTED] used in the [REDACTED] must be [REDACTED] or the
[REDACTED].

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