

## **SPECIAL 510(k): Device Modification Decision Summary**

**To:** THE FILE

**RE:** DOCUMENT NUMBER K143592

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This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable:

1. The name and 510(k) number of the SUBMITTER'S previously cleared device.

GAMMA PHAGE LYSIS ASSAY FOR THE IDENTIFICATION OF BACILLUS ANTHRACIS  
510(k) Number: K051794

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).
3. A description of the device **MODIFICATION(S)**:  
The modification presented in this special 510(k) consisted of changing the *Bacillus anthracis* positive control from the specified Pasteur strain, to the Sterne strain. The reason for the change was to allow laboratories to maintain a non-listed agent (Sterne strain), versus the Pasteur strain that is a biological select agent, and reduce logistics burdens imposed by the use of a select agent strain without compromising the assay performance. In addition, supporting data in the form of potency testing was provided demonstrating that while the *Bacillus anthracis* Sterne strain is less sensitive to gamma phage lysis than the Pasteur strain, it is more representative of the gamma phage reaction when compared with wild-type *Bacillus anthracis* (e.g., Ames strain) and is therefore a more appropriate positive control.

In addition to changing the *Bacillus anthracis* positive control strain from Pasteur to Sterne, the instructions for use has been updated to include some additional sources and forms (viable lyophilized cells and/or spore suspension) of both the positive (*Bacillus anthracis*) and negative control (*Bacillus cereus*) materials. As with the original 510k submission, the control materials are listed as "available controls". Prior to use these materials are used to prepare fresh cultures of both the positive or negative controls that are then used as quality control materials for the gamma phage lysis assay. Testing and validation information was provided for the control materials BC3366, BC3133 and BC3367 and Certificate of Analysis (COAs) were provided for the control materials ATCC14579 (from ATCC) and 19102 (from Colorado Serum Company).

The **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

4. **Comparison Information:**

Similarities to applicant's legally marketed predicate device include:

The procedure for running the Gamma Phage Lysis Assay for testing isolated colonies of gram positive *bacilli* with colony morphology typical of *Bacillus anthracis* outlined in the Gamma Phage Lysis Assay for the Identification of *Bacillus anthracis* Instructions for Use remains unchanged. In addition the procedure for running the positive and negative controls as part of the Quality Control testing remains unchanged and involves preparation of fresh cultures of the control strains by inoculation of a Sheep Blood Agar (SBA) plate – streak for isolation and incubate overnight.

**Table 1:** Similarities between the predicate device (K051794) and the proposed device (K143592)

Feature	K051794 Predicate Device	K143592 Proposed Device
<i>Bacillus anthracis</i> Gamma Phage Suspension	<i>Bacillus anthracis</i> Gamma Phage Suspension 0.5 ml (BP3123)	Same
Specimen	Gamma Phage Assay should be performed on isolated colonies of gram positive <i>bacilli</i> with colony morphology typical of <i>B. anthracis</i>	Same
Materials required but not supplied	<ul style="list-style-type: none"> <li>• 5% Sheep Blood Agar plate</li> <li>• Inoculating loops, 1µl and 10 µl</li> <li>• Aerosol resistant pipette tips</li> <li>• Disinfectant</li> </ul>	Same
Equipment required	<ul style="list-style-type: none"> <li>• Pipettor, 5-50 µl</li> <li>• Incubator, 35+/- 2 °C</li> <li>• Biological Safety Cabinet, Class II</li> <li>• Refrigerator, 2-8 °C</li> </ul>	Same

Differences to applicant's legally marketed predicate device include:

The Gamma Phage Lysis Assay for the Identification of *Bacillus anthracis* Instructions for Use has been updated to include *Bacillus anthracis* Sterne strain as the positive control. In addition the "materials" section has been updated to include some additional sources and forms (viable lyophilized cells and/or spore suspension) of both the positive and negative control materials (see Table 2).

**Table 2:** Differences between the predicate device (K051794) and the proposed device (K143592)

Feature	K051794 Predicate Device	K143592 Proposed Device
Positive Control	<i>Bacillus anthracis</i> Pasteur strain spore suspension 1.0 ml (BC3132)	<i>Bacillus anthracis</i> Sterne strain viable lyophilized cells (BC3366)  Colorado Serum Company (19102) Anthrax Spore Vaccine – 1.0 ml suspension of viable <i>Bacillus anthracis</i> Sterne strain 34F2 spores
Negative Control	<i>Bacillus cereus</i> spore suspension 1.0 ml (BC3133)	<i>Bacillus cereus</i> spore suspension 1.0 ml (BC3133) - same  <i>Bacillus cereus</i> lyophilized cells (BC3367)  ATCC 14579 – <i>Bacillus cereus</i> freeze-dried (lyophilized)
Reporting – Capsule Staining Techniques	A positive gamma phage result, in conjunction with a positive result for capsule, is considered confirmatory identification of <i>B. anthracis</i> . Capsule may be demonstrated by colony morphology on bicarbonate agar after incubation in enhanced CO <sub>2</sub> or by staining techniques (India ink, M'Fadyean, or capsule DFA).	A positive gamma phage result, in conjunction with a positive result for capsule, is considered confirmatory identification of <i>B. anthracis</i> . Capsule may be demonstrated by colony morphology on bicarbonate agar after incubation in enhanced CO <sub>2</sub> or by staining techniques (India ink or M'Fadyean).  Difference - Capsule DFA removed.

Contact information for the additional sources (Colorado Serum Company and ATTC) was provided with the following disclaimer "*Names of vendors or manufacturers are provided as examples of suitable product sources. Inclusion does not imply endorsement by the Centers for Disease Control and Prevention, the Department of Health and Human Services or the Federal Bureau of Investigation*". The "interpretation of results" section has also been updated with a description and

images of what to expect when using the *Bacillus anthracis* Sterne strain as the positive control. However, it does not change the interpretation of the quality controls or the wild type strains. The “reporting” section has been updated to (1) remove capsule DFA as it is no longer used as a staining technique for this assay and (2) to include the requirement that all test results (positive, negative, inconclusive) should be submitted to CDC as outlined in the Data Messaging Policy on the secure LRN website. The Gamma Phage Lysis Assay for the Identification of *Bacillus anthracis* Instructions for Use has also been updated to include a “procedure notes” section and “credit” section – which outlines the agencies involved in the development of the assay.

The package inserts for the positive and negative control materials distributed by CDC for the LRN - BC3366, BC3367 have been updated/ included to reflect the modifications outlined in the table above. Minor modifications to update contact emails were also included.

**5. Design Control Activities Summary:**

A “Declaration of Conformity with Design Controls” statement was submitted for the manufacturing facility and verification activities. The statements indicate that:

1. The manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review – signed by the Chief of the Scientific Products and Support Branch.
2. The validation activities, as required by the risk analysis, for the modification were performed by the designated individuals and the results demonstrated that the predetermined acceptance criteria were met - signed by a supervisory research microbiologist.

**6. Truthful and Accuracy Statement, a 510(k) Summary or Statement, Package Inserts, Labels Instructions for Use and the Indications for Use Enclosure:**

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter’s description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.