

RAMP® Anthrax Test Package Insert

Note: Failure to follow documented procedures may result in invalid and/or erroneous results. Read the entire Package Insert prior to use.

INTENDED USE

The RAMP Anthrax Test is intended for the screening of environmental samples for the presence of *Bacillus anthracis* spores (BA), the causative agent of anthrax disease. A positive test result indicates the presence of BA at or above the detectable concentration.

This test is intended for trained users only. It is not for use by the general public or individuals untrained in the handling of hazardous materials. This test is not to be used for human medical diagnostic purposes.

PRINCIPLES OF THE TEST

The RAMP Anthrax Test is an immunochromatographic test for the detection of BA. To begin the test of suspect materials or areas, powders are sampled using a dry Microbrush® while liquids are sampled with a Swab and surfaces are sampled with a pre-wetted Swab.

The sample is then recovered into an Anthrax Sample Buffer Vial. A measured amount of the sample in buffer is transferred to the sample well of the Anthrax Test Cartridge using the supplied pipette and Anthrax Assay Tip. The Test Cartridge is then placed into the RAMP Reader.

In the Test Cartridge, the buffered sample migrates along a test strip. Fluorescent particles, coated with anti-BA antibodies, bind to BA if present in the sample. As the sample migrates, BA-bound particles are immobilized at the detection zone, and additional control particles are immobilized at the internal control zone.

The RAMP Reader then measures the amount of fluorescence emitted by the particles bound at each zone. Using a ratio between the two fluorescence values, a "POSITIVE" or "NEGATIVE" test result is determined and displayed on the Reader. For further information on the use of the RAMP Reader refer to the Operator's Manual.

Materials Provided	Amount
RAMP Anthrax Test Cartridges	25
Anthrax Assay Tips (packaged with Test Cartridges)	25
Anthrax Sample Buffer Vials	25
TriContinent MiniPet™ – 70 µL	1
Disposable Liquid Sampling Swabs	10
Disposable Powder Sampling Microbrushes®	25
Lot Card	1
Package Insert	1
Marking Pen	1

MiniPet™ is a trademark of TriContinent Inc.

Microbrush® is a registered trademark of Microbrush International

Equipment required, but not provided	Equipment recommended, but not required
RAMP Reader	Y Small 40 character serial printer and accessories Y Personal computer with RS-232 connector

SAMPLE COLLECTION AND PREPARATION

Sample Collection – Visible Powders

1. Obtain an Anthrax Sample Buffer Vial from the Kit. With the lid on, hold the lid of the Vial and quickly flick your wrist in a downward motion to ensure that no liquid is retained in the Vial lid.
2. Remove a Powder Sampling Microbrush from its container, holding it by the handle so as not to touch the head.
3. Lightly touch the dry head of the Microbrush to the surface of the powder, taking care not to pick up too much powder.
4. Open the Vial, dip the head of the Microbrush into the buffer and stir for 10 seconds. Avoid foaming the buffer.
5. Pull the Microbrush from the buffer and rotate against the inside of the Vial to remove excess liquid.
6. Discard Microbrush. Proceed to “Reader Set-up” then “Analysis Procedure”.

Sample Collection – Area Swipe

1. Obtain an Anthrax Sample Buffer Vial from the Kit. With the lid on, hold the lid of the Vial and quickly flick your wrist in a downward motion to ensure that no liquid is retained in the Vial lid.
2. Remove a Liquid Sampling Swab from its container, holding it by the handle so as not to touch the absorbent end.
3. Open the Vial, dip the absorbent end of the Swab into the buffer and soak for 3 seconds.
4. Pull the Swab from the buffer and rotate against the inside of the Vial above the liquid to remove excess liquid.
5. Swipe the suspect area using the moistened end of the Swab.
6. Place the absorbent end of the Swab back into the buffer and stir the Swab in the buffer for 10 seconds. Avoid foaming the buffer.
7. Pull the Swab from the buffer and rotate against the inside of the Vial to remove excess liquid.
8. Discard Swab. Proceed to “Reader Set-up” then “Analysis Procedure”.

Sample Collection – Liquids or Suspensions

1. Obtain an Anthrax Sample Buffer Vial from the Kit. With the lid on, hold the lid of the Vial and quickly flick your wrist in a downward motion to ensure that no liquid is retained in the Vial lid.
2. Remove a Liquid Sampling Swab from its container, holding it by the handle so as not to touch the absorbent end.
3. Dip the absorbent end of the dry Swab into the suspect liquid and soak for 3 seconds.
4. Open the Vial, dip the absorbent end of the Swab into the buffer and stir the Swab in the buffer for 10 seconds. Avoid foaming the buffer.
5. Pull the Swab from the buffer and rotate against the inside of the Vial to remove excess liquid.
6. Discard Swab. Proceed to “Reader Set-up” then “Analysis Procedure”.

Reader Set-up

1. Turn on the Reader.
2. If not previously done, remove the Lot Card from its pouch and insert the Lot Card for the Test Cartridge lot being used into the Lot Card slot below the keypad on the Reader. Once the Lot Card information has been uploaded, return the Lot Card to its pouch.

Warning: Avoid touching the contacts at the end of the Lot Card

3. Press [Enter] to select RUN TEST on the RAMP Reader.
4. Enter Sample ID (user defined up to 20 alphanumeric characters), and if the User ID feature has been enabled, select or enter User ID.

For detailed information regarding RAMP Reader or Lot Card operation, refer to the RAMP Environmental Reader Operator’s Manual

Analysis Procedure

1. Open a kit pouch containing a Test Cartridge and Assay Tip. Place the Test Cartridge on a clean, dry, level surface.
2. Firmly place the single-use Assay Tip on the 70 µL MiniPet. Check to confirm that there is a pink dot on the inside surface of the Assay Tip.
3. If required, write the Sample ID on the Test Cartridge with the marking pen provided.
4. Fully depress the MiniPet plunger and insert the Assay Tip into the Sample Buffer Vial containing the suspected agent sample, close to the bottom of the Vial (not touching).

5. Holding the Vial at eye level, gently release the plunger to fill the Assay Tip. Avoid pressing against the bottom of the Vial, which may block the Tip.
6. Mix the sample by slowly pressing and releasing the plunger 10 times (2 seconds per cycle), taking care each time to eject all of the sample into the Vial and to draw only liquid and no air into the Assay Tip. This will prevent foaming.
7. Check that the sample is fully mixed by confirming that the pink dot is no longer visible on the inside of the Assay Tip.
8. Fully depress and gently release the plunger to fill the Assay Tip with sample (no foam).
9. Position the filled Assay Tip directly over the sample well on the Test Cartridge and fully depress the plunger to dispense the entire sample into the sample well. (Disregard any remaining droplet within the Assay Tip). Remove and dispose of Assay Tip.
10. Immediately (within 30 seconds) insert the Test Cartridge into the Reader and then press until firm resistance is felt.
NOTE: Do not try to hold onto or force the Test Cartridge into the Reader once resistance is felt.
11. The Reader accepts the Test Cartridge and begins timing the test development process. Within approximately 15 minutes, when the test is complete, the Reader will scan the Test Cartridge, perform data analysis and report the result from the RAMP Anthrax test on the LCD display.
12. Remove the used Test Cartridge from the Reader when prompted to do so by the Reader LCD display. Dispose of the Test Cartridge and Vial.

CALIBRATION PROCEDURES – LOT CARD

Each RAMP Anthrax Test kit includes a Lot Card that is individually packaged in an anti-static pouch. The Lot Card provides information specific to the Kit Test Cartridge lot, including lot number, expiration date and Negative/Positive threshold value. For further details, refer to the Operator's Manual on loading lot-specific information. Insertion of the Lot Card into the Reader is the only calibration necessary.

QUALITY CONTROL

System Quality Control (QC)

- n The RAMP Reader has error checking and self-diagnostic functions that assure procedural control. These include algorithms and measurements used to confirm acceptable operator technique, sample handling, and assay performance.
- n If a problem is detected, a user message is displayed.
- n Sample results are displayed only after all QC performance requirements have been met.

Test Cartridge QC

- n Each Test Cartridge has a control zone that is scanned as part of the test protocol.
- n Control limits for each lot of Test Cartridge are established during the manufacturing process and are included in the specific Lot Card. If a control result does not meet specifications, the sample result is not reported and an error message is displayed.

Run Messages

There are four particular Run Messages that may be resolved by a retest, beginning with the SAMPLE COLLECTION AND PREPARATION section, using a new sample, Swab or Microbrush, Sample Buffer Vial, Test Cartridge and Assay Tip. These are:

- n (SAMPLING ERROR # 1) – This message indicates that the sample flow occurred before the Test Cartridge was inserted into the Reader. This may be because: 1) there was an unacceptable delay between sample addition to the Cartridge and insertion of the Cartridge into the Reader, 2) an already-used Cartridge was inserted, or 3) a Cartridge was re-inserted that had already been rejected by the Reader.
- n (SAMPLING ERROR # 2) – This message indicates that the sample flow was not detected. This may be because: 1) the sample pad is clogged with excess powder, 2) the sample was insufficiently mixed with the Assay Tip, 3) there was less than 70 µL of diluted sample in buffer transferred to the Cartridge, or 4) the supplied Assay Tip was not used. If repeating the test does not solve the problem, attempt to pick up less powder or dilute the raw sample.
- n (LOW SIGNAL) – This message may be due to insufficient sample being transferred to the Test Cartridge or insufficient mixing of the sample.
- n (HIGH BACKGROUND SEE PACKAGE INSERT) – This message may be due to interfering substances in the sample. Dilute the raw sample or retest, attempting to pick up less powder.

1. If a Swab contains 4000 or more BA spores (equivalent to 2000 spores per Test Cartridge) the RAMP Anthrax Test will give a positive result. Due to the variable nature of spore populations and preparations, actual test sensitivity can vary for any given sample containing BA.

2. If repeated tests give unexpected or inconsistent results, contact Technical Support.

WARNINGS AND PRECAUTIONS

- n For environmental testing use only, not for *in vitro* diagnostic use.
- n Use appropriate precautions in the collection, handling, storage and disposal of raw or diluted samples and used kit contents.
- n Discard and do not use any visibly damaged cartridges, or the contents of any Cartridge / Assay Tip pouch with a damaged seal.
- n Do not use kit contents after the expiration dates.
- n Do not mix components from different kits.
- n The Test Cartridge should be discarded after a single use. DO NOT REUSE.
- n Sample must be applied to sample well only.
- n If sample has spilled on the outside surface of the Test Cartridge, do not insert into the RAMP Reader. This may cause permanent contamination or damage to the RAMP Reader.
- n If not used within 60 minutes of opening the pouch, dispose of unused Test Cartridges.

STORAGE INSTRUCTIONS

Anthrax Test Cartridges and Sample Buffer Vials should be stored at 2 - 24°C (36 - 75°F).

LIMITATIONS OF PROCEDURE

- n The results obtained from the use of this product should be used only as an adjunct to other confirmational procedures.
- n Adulterant such as bleach in the specimen may produce an erroneous result. If adulteration is suspected, the test should be repeated with a new or diluted sample.
- n A positive test result does not provide any indication of the concentration of BA.

ANTHRAX DETECTION PROTOCOL

If a test result is "POSITIVE", follow State and Federal Law concerning the handling of INFECTIOUS SUBSTANCES. Usually these protocols include:

- § Handle all material with appropriate personal protective equipment.
- § Avoid generating any kind of aerosol.
- § Secure the area to prevent further exposure.
- § Bag and secure a sample, including the Swab, making sure not to contaminate the outer bag.

If the incident poses an immediate threat, contact the appropriate authorities, which may include:

- § Local Hazardous Material Unit or State Public Health Office
 - § Local FBI Office - WMD Coordinator
 - § Domestic Preparedness Office 1-800-424-8802
 - § Center for Disease Control Bioterrorism Unit 1-770-488-7100
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