

BROOKHAVEN NATIONAL LABORATORY Safety & Health Services Division	NUMBER IH105394
	REVISION FINAL rev1
INDUSTRIAL HYGIENE GROUP Standard Operating Procedure: Program Procedure	DATE 05/06/08
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Subject: Chemical and Biological Agents Emergency Response	
<i>Bio Threat Alert (BTA®) Test Strips</i> <i>for Biological Agent Screening</i>	

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1.0 Purpose & Scope

Purpose: The purpose of this procedure is to document the method to detect the presence of microbial agents using *Tetracore Bio Threat Alert™ Test Strips* (BTA™). With this system, relatively inexperienced field testers are able to gain rapid “go/no-go” results indicating the presence of certain biological agents. The samplers use agent specific labeled-antibody conjugate (monoclonal and polyclonal antibodies) based impregnated on a thin layer membrane. The labeled antibody changes color when exposed to specific biological agent(s). The exposed test strip is compared to a built in reference marker (control) to verify the presence of a biological agent and the functionality of the test strip.

Scope: The BTA Test Strip system is designed for collection of environmental samples, and is not to be used for samples collected from humans for medical diagnosis. The strips are capable of detecting agents for which the specific test strips have been purchased. The SHSD IHG potentially maintains an inventory of BTA Test Strips for (depending on needs):

- Anthrax and
- Botulinum Toxin (Bot Tox).

This SOP cannot anticipate all hazards and exposure scenarios that may be encountered in an actual emergency. Thus this SOP does NOT:

- Establish any mandatory action that must be taken.
- Limit actions that in the judgment of the IHG personnel are prudent and necessary.
- Limit the professional judgment of the IH Group personnel responding to an event.

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- Authorize IHG personnel to place themselves or others at an unacceptable or preventable risk.

2.0 Responsibilities

- 2.1 SHSD personnel assigned a role in the BNL Emergency Plan are responsible to act within SHSD's emergency response SOPs and within the overall requirements in the BNL Emergency Plan and OSHA HazWoper requirements.
- 2.2 This procedure will be implemented through the SHSD Industrial Hygiene Group to address concerns of the presence of biological agents in emergency situations. Only persons who thoroughly understand this procedure should use the BTA Test Strips.

3.0 Definitions

- 3.1 ***BTA Test Strip***: A biological agent (bacteria, virus, or toxin) detector system manufactured by Tetracore and sold by Alexeter Technologies, LLC.

4.0 Prerequisites

- 4.1 **Qualifications**: Only persons who have met all qualification requirements listed in Section 7 may use this SOP.

5.0 Precautions

- 5.1 The site of any incident may be a crime scene. Do not enter the area or take any samples without the permission of the security/criminal investigation authority at the site.
- 5.2 Only persons who thoroughly understand this procedure and have demonstrated competency to the satisfaction of their supervision should use the system.
- 5.3 Prior to testing with BTA Test Strips, determine if the *Expiration Date* printed on the box of strips has not been exceeded. Do not use strips that are older than the expiration date. Discard the BTA strip if it has not been stored at 15° to 30°C and/or if the pouch is not sealed.
- 5.4 Testing on clay, gravel and mulch samples is not recommended.

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5.5 **Hazard Determination:** This test may involve exposure to a hazardous agent. The level of exposure may be above safe levels (no Occupational exposure limits are set). Because it will be an emergency situation, PPE will typically be the most appropriate means of exposure control.

5.6 **Personal Protective Equipment**

5.6.1 Hand: Hand protection is required. Contact with contaminated media and contaminated surface requires the use of gloves. Exam-style Nitrile or natural latex rubber gloves are acceptable.

5.6.2 Body: Tyvek suit is required.

5.6.3 Foot: Foot protection is required to prevent the spread of contamination. Booties or rubber boot coverings are required.

5.6.4 Respiratory: Respiratory protection is required. HEPA filter APR, PAPR air line respirators, or SCBA are acceptable.

5.6.5 Eye: Safety Glasses with side shields are required unless a full-face respirator is used.

5.7 **Waste Disposal/ Environmental Impact:** Hazardous Waste is generated in the form of used BTA Test Strips and used PPE. Do not discard exposed test strips that have indicated a color change in normal trash. Place the strip in a zip lock plastic bag and consult with the Waste Management Division on the waste disposal procedures.

6.0 **Procedure**

6.1 **Equipment:**

6.1.1 **BTA Test Strip Kits:** Tetracore/Alexeter Technologies, LLC. (Contains 25 BTA test strips; bulb droppers; cotton-tipped swabs; collection vials; 5 ml of buffer.)

- S-1001: Anthrax.
- S-1003: Botulinum Toxin

6.1.2 Sample Collection Kit (Contains alcohol pads, tweezers, scissors; cotton-tipped swabs; collection vials; scoops, permanent marker, bottles of buffer.)

6.1.3 PPE: gloves, suits, booties, respirator.

6.1.4 Zip lock bag.

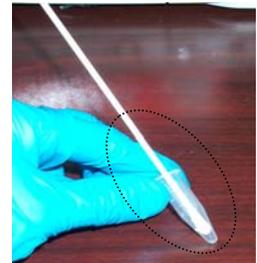


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6.2 Sample collection and Preparation: Swipe Samples or Bulk

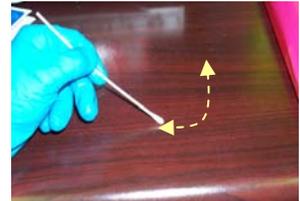
6.2.1 Fill a sample vial with 1 ml of Sample Buffer.

6.2.2 Dampen an indicator swab with the Sample Buffer by placing it in the sample vial and rotating it.



Step 6.2. 1 & 6.2.4

6.2.3 With gloved hands, swipe the area to be tested, rotating the swab tip. Bulk powder can be scooped up and placed directly into the vial.

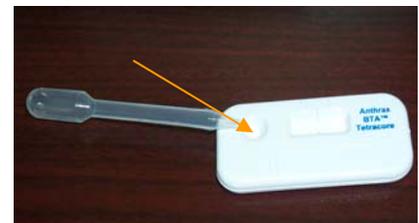


Step 6.2.3

6.2.4 When finished sampling, place the applicator tip into the sample vial and mix for 10 seconds (rotate the tip). Rotate and press the tip along the inside of the vial to remove excess liquid before removing.

6.2.5 Close the vial cap and agitate vigorously. Allow large particles to settle to the bottom (15-30 seconds).

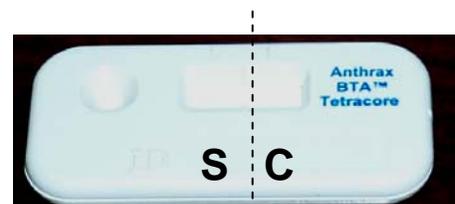
6.2.6 Using the disposable bulb dropper, remove the liquid from the vial, (do not pull but particles from the bottom).



Step 6.2.6 & 6.2.7

6.2.7 Remove the BTA strip from the protective pouch and place on a flat level surface. Label the strip with an identifying number using the marker. Place **5 to 6 drops** (0.15 ml) into the SAMPLE PORT of the BTA Test Strip.

6.3 **Determining the Results:** Read the results after 15 MINUTES. Colored lines that appear after 20 minutes are not valid and should be ignored. Positive results may be observed in as little as 30 seconds depending on the concentration of the biological agent.



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- **Negative Results:** The test is negative if a single colored line appears only in the **C** (control) window.
- **Positive Results:** The test is positive if two colored line appear. One colored line will appear in the **C** (control) window. Any colored line in the **S** (sample) window should be considered positive. The colored **S** line may be lighter or darker than the **C** control line.
- **Invalid test:** The test is invalid if no colored line appears in the **C** (control) window, even if a colored line appears in the **S** (sample) window.

6.4 **Validating the results:** A false negative may occur when levels of specific biological threat agents are below the detectable concentration level (sensitivity) of the tests. The test may produce a negative or positive result for cross reactants. See Attachment 9.1.

6.5 **Recording the Result:** Record results on the “BNL Direct Reading Instrument” form or an equivalent form.

6.6 **Waste Disposal:** After BTA Test Strip has been used and turned a color indicating exposure to a biological agent, place the paper into a zip lock bag. Label the bag with a Biohazard sticker and dispose of the bag and used PPE via the Waste Management Division. Determination of the hazardous waste category can be determined based on the chemical reactants on the paper.



7.0 Implementation and Training

- 7.1 The SHSD IHG qualifies personal who perform emergency response work by insuring knowledge of this procedure.
- 7.2 Responders need to have OSHA HazWoper Section (q.) qualification comparable to their role in the response.
- 7.3 Responders need to meet all training requirement of the BNL Emergency Response Plan comparable to their role in the response.

8.0 References

- 8.1 *Tetracore Anthrax BTA Test Strip product sheet.*
- 8.2 *Tetracore Botulinum Toxin BTA Test Strip product sheet.*

The only official copy is on-line at the SHSD IH Group website.
 Before using a printed copy, verify that it is current by checking the document issue date on the website.

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9.0 Attachments

9.1 *Tetracore* Evaluations for Interfering Substances

9.2 *Qualification Form: Job Performance Measure*

10.0 Documentation

Document Development		
Prepared By: <i>(signature/date on file)</i> R. Selvey 04/29/02 Certified Industrial Hygienist	Reviewed By / Date: <i>(signature/date on file)</i> K. Erickson 05/02/02	Approved By / Date: <i>(signature/date on file)</i> R. Selvey 05/13/02 IH Group Leader
ESH Coordinator/ Date: <i>none</i>	Work Coordinator/ Date: <i>none</i>	SHSD Manager / Date <i>none</i>
QA Representative / Date: <i>none</i>	Training Coordinator / Date: <i>none</i>	Filing Code: IH52
Facility Support Rep. / Date: <i>none</i>	Environ. Compliance Rep. / Date: <i>none</i>	Effective Date: 05/13/02
ISM Review - Hazard Categorization <input checked="" type="checkbox"/> High <input type="checkbox"/> Moderate <input type="checkbox"/> Low/Skill of the craft	Validation: <input type="checkbox"/> Formal Walkthrough <input type="checkbox"/> Desk Top Review <input type="checkbox"/> SME Review Name / Date:	Implementation: Training Completed: Tracked in BTMS Procedure posted on Web: 05/06/08 Hard Copy files updated: 05/06/08 Document Control on forms: 05/06/08

Revision Log
Purpose: <input type="checkbox"/> Temporary Change <input type="checkbox"/> Change in Scope <input checked="" type="checkbox"/> Periodic review <input type="checkbox"/> Clarify/enhance procedural controls Changed resulting from: <input type="checkbox"/> Environmental impacts <input type="checkbox"/> Federal, State and/or Local requirements <input type="checkbox"/> Corrective/preventive actions to non-conformances <input checked="" type="checkbox"/> none of the above Section/page and Description of change: Eliminated 5.1. Added SCBA to 5.5.4. Removed words "Biothreat Alert Kit" from 6.1 Revised format of Section 10. Attachment Added Attachment 9.2 JPM Qualification form. SME Reviewer/Date: <i>(signature on file)</i> R. Selvey 05/06/08

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Attachment 9.1

Tetracore Evaluations for Interfering Substances

BTA Strip	Substance tested	Status of Interference
Anthrax	SEB toxin	None at 1 ug/ml
	Ricin Toxin	None at 1 ug/ml
	Botulinum Toxin A & B	None at 1 ug/ml
	B. globigii Spore	None at 1 ug/ml
	B. globigii Vegetative Cells	None at 1 ug/ml
	B. thuringiensis Spore	None at 1 ug/ml,
	B. thuringiensis Vegetative Cells	None at 1 ug/ml
	Bovine Serum albumin	None at 1 ug/ml
	Ovalbumin	None at 1 ug/ml
	Yersinia pestis	None at 1 ug/ml
	F. Tularensis	None at 1 ug/ml
	Acetaminophen	None at 1 ug/ml
	Naproxin sodium	None at 1 ug/ml
	Talc; Mulch; Red Clay; Gravel	None at 1 ug/ml
Botulinum Toxin	SEB toxin	None at 1 ug/ml
	Ricin Toxin	None at 1 ug/ml
	B. anthracis Spore	None at 1 ug/ml
	B. anthracis Vegetative Cells	None at 1 ug/ml
	B. cereus	None at 1 ug/ml
	B. globigii Spore	None at 1 ug/ml
	B. globigii Vegetative Cells	None at 1 ug/ml
	B. thuringiensis Spore	None at 1 ug/ml,
	B. thuringiensis Vegetative Cells	None at 1 ug/ml
	Bovine Serum albumin	None at 1 ug/ml
	Ovalbumin	None at 1 ug/ml
	Yersinia pestis	None at 1 ug/ml
	F. Tularensis	None at 1 ug/ml
	Acetaminophen	None at 1 ug/ml
Naproxin sodium	None at 1 ug/ml	
Talc; Mulch; Red Clay; Gravel	None at 1 ug/ml	

**BTA Test Strip Operation
Job Performance Measure (JPM) Completion Certificate**

Candidate's Name	Life Number:
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Equipment Operation Practical Skill Evaluation: Demonstration of Methodology

Criteria	Qualifying Performance Standard	Unsat.	Recov.	Satisf.
Scene Preservation	Understands that the site of any incident may be a crime scene. Knows not enter the area or take any samples without the permission of the security/criminal investigation authority at the site.			
Test Equipment	Knows to check the BTA Test Strips to determine if the <i>Expiration Date</i> printed on the box of strips has been exceeded prior to testing.			
Limitation	Knows that testing on clay, gravel and mulch samples is not recommended, due to possible interferences.			
PPE	Describes the correct PPE required for this task.			
Sample collection	Demonstrates the proper sample collection method using the swab, ampoule, and solution.			
Sample Preparation	Demonstrates the proper technique to mix the solution and deliver the correct amount of solution to the test strip via the dropper.			
Reading the Sample Results	Demonstrates knowledge in the test indication patterns, and the proper holding time prior to reading the test strip.			
Recording Results	Knows the correct form to record sampling results.			
Disposal	Describes the correct method for disposal of PPE, spent samples, and Media.			

I accept the responsibility for performing this task as demonstrated within this JPM and the corresponding SOP.

Candidate Signature:	Date:
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I certify the candidate has satisfactorily performed each of the above listed steps and is capable of performing the task unsupervised.

Evaluator Signature:	Date:
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