

3-Agent Biothreat Assay

Detect. Identify. Move on.



defining *on-demand* molecular testing.

3-Agent Biothreat Assay:

The GeneXpert® 3-Agent Biothreat Assay is designed for surveillance of the etiologic agents of anthrax, plague and rabbit fever (tularemia) in environmental samples.

screening & identification in one kit:

Cepheid's 3-Agent Biothreat Assay consists of a simple two-cartridge system. Either cartridge can be used for screening, or to rule out a substance in question. If one of the three targets is detected during a single cartridge test, the second cartridge is used to identify the specific agent in question.

accurate:

GeneXpert® System and 3-Agent Biothreat Assay use the same proven technology driving the United States Postal Service Biohazard Detection System. With over 4.5 million anthrax

tests now run, producing no false positives, Cepheid's technology has become today's "gold standard" in biothreat detection.

rapid:

The 3-Agent Biothreat Assay screening test can be completed in just 35 minutes using either of the included cartridges. If identification is needed, a second cartridge must be run, making total time to identification just 70 minutes.

minimal impact:

This unprecedented combination of speed, accuracy, and mobility combine to minimize life disruptions while on-site testing is performed.

Xpert:
in action

prevention:

The sensitivity of Cepheid's 3-Agent Biothreat Assay delivers results that can be acted upon with confidence. This includes ruling out a suspicious substance or proceeding with appropriate treatment for those exposed to biohazards.

integrated:

The GeneXpert® System is the only system that combines sample preparation with real-time PCR amplification and detection for fully integrated and automated nucleic acid analysis. The system rapidly purifies, concentrates, detects, and identifies targeted nucleic acid sequences.

flexible:

The GeneXpert® System can be configured from 1-4 modules depending on the throughput required. Additional modules can be purchased at any time to expand the system as required.

Xpert:
by design

easy to use:

The GeneXpert® System requires minimal hands-on time. It is designed for easy operation by non-laboratory personnel. Users simply place sample in a self-contained cartridge and the GeneXpert® System does the rest.



Performance Data:

Testing conducted by USAMRIID.

Limit of detection achieved in either buffer or environmental air samples.

		Limit of Detection			
		Cartridge 1		Cartridge 2	
Agent	<i>B. anthracis</i>	pX02	<200 cfu/ml	pX01	<200 cfu/ml
	<i>F. tularensis</i>	Tul4	<100 cfu/ml	fopA	<100 cfu/ml
	<i>Y. pestis</i>	CAF1	200 cfu/ml	PLA	200 cfu/ml

Organisms used in testing were irradiated

Inclusivity & Exclusivity:

Confidence in your results.

100% inclusive — all species-specific strains were detected.

100% exclusive — no species from the same or different genera were detected.

Four separate panels: DNA from 139 bacterial strains DNA was tested on the SmartCycler® System. Samples were spiked at 1 pg DNA.

Cartridge 1 reagent beads Ba:pX02, Ft: Tul4, Yp: CAF1

Panel Name	Panel Total	#Species-Specific	Positives	Negatives
Primary	60	3 ^a	3 ^b	57
Anthrax	34	6	6	28
Tularemia	12	10	10	2
Plague	33	5	5	28
Total	139	24	24	115

Cartridge 2 reagent beads Ba:pX01, Ft: fopA, Yp: PLA

Panel Name	Panel Total	#Species-Specific	Positives	Negatives
Primary	60	3 ^a	3 ^b	57
Anthrax	34	8	8	26
Tularemia	12	10	10	2
Plague	33	6	6	27
Total	139	27	27	112

A. One strain for each agent (Ba, Ft and Yp) B. pX02, Tul4, CAF1 C. pX01, fopA, PLA

Simulant Testing:

Get results when and where you need them.

Either cartridge can be used to detect *Bacillus globigii* for simulant testing purposes. Study was performed at Cepheid using washed *Bg* spores.

		Cycle Threshold (Ct)	
		Cartridge 1	Cartridge 2
<i>Bg</i> spores	Negative	0	0
	375	37.9	43
	750	37.3	37.8
	1,500	36	37.5
	3,000	35.9	37.1
	6,000	34.4	35
	12,000	33.3	34.7

The GeneXpert® advantage: **Simplicity**

- Fully integrated sample processing and PCR
- The performance of PCR without the labor and facilities of traditional PCR
- Rapid results improve human and operational outcomes
- Fully integrated reagent and instrument system for accuracy and reproducibility



1. Dispense Sample into port S



2. Dispense Reagent 1 into port 1



3. Dispense Reagent 2 into port 2



Total hands-on time = 2 minutes



4. Insert cartridge and start assay

Ordering Information

GeneXpert 3-Agent Biothreat AssayCatalog No. GXBT3A-100N-010
(10 cartridges with reagents)

References:

1. Winegar R, Knittel J, Wolack J, Andreotti P, Sakai S, Tholath J, McMillan W, Swenson D, and Ryan JR. Evaluation of ASD Collection Device and GeneXpert System for Recovery and Detection of *Bacillus anthracis*. Abstract and poster presented at the Cambridge Healthtech Institute DNA Forensics Conference. McLean, VA. June 2004.
2. Ulrich MP, Coyne SR, Craw PD, Christensen DR, Abshire TA, Sakai S, Weir F, Tsai J, Swenson D, Tholath J, and Norwood DA. Evaluation of the Cepheid GeneXpert System and Four-Plex Cartridge for Detecting *Bacillus anthracis*. Abstract and poster presented at the American Society for Microbiology Conference. New Orleans, LA. May 2004.
3. Ulrich MP, Christensen DR, Coyne SR, Craw PD, Henchal EA, Sakai SH, Swenson D, Tholath J, Tsai J, Weir AF, and Norwood DA. Evaluation of the Cepheid GeneXpert System for Detecting *Bacillus anthracis*. *Journal of Applied Microbiology*. 2006; 100: 1011-1016.
4. Bioterrorism. Centers for Disease Control and Prevention, Emergency Preparedness and Response. <http://www.bt.cdc.gov/bioterrorism/>(accessed March 30, 2006).

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