



# FAQs

## Guardian Reader System

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### 1. Why should I perform on-site testing if we routinely send the sample to a central lab for confirmatory testing?

#### AS AN ASSIST to Confirmatory Testing

A reliable, presumptive test result gives the technical staff at the central lab a head start on the nature of the threat. Preliminary test results often can help the technical staff to focus more quickly on the lab tests required to confirm the sample's identity.

#### DELAYS Become More Important if Toxins are Involved

rapid onset illnesses resulting from an intentional release of these agents.

Although anthrax threats are the leading hoax, and anthrax inhalation has a delay of several days before the onset of symptoms, leading toxin threats such as botulism, SEB & ricin provide no such time cushion. They can produce deleterious effects in hours. Reliable, on-site testing can assist local medical officials, allowing them to ascertain the cause of

#### GUIDANCE for First Responders

attempting to control a biological threat situation.

Local officials need to make rapid decisions regarding the magnitude of the response to a biological threat situation. The "what ifs" are too numerous to mention. Any reliable information that can be obtained helps to provide confidence and guidance to any local command

#### EMOTIONAL & Psychological Effects

provide critical information; they are not left to inform potential victims: "Someone will get back to you in 24-48 hours with more information."

With results from on-site testing, both potential victims and emergency personnel can leave the scene with a more secure sense of comfort and control. This is especially true if the results are negative. Reliable screening test results give local command officials the power to

#### SAFETY ISSUES for First Responders

Well-documented and precise test results from the Guardian Reader System can be delivered directly into the hands of law enforcement officials, alleviating the conflict that invariably arises at emergency events that become crime scenes.

### 2. If no substances, except anthrax, give positive results with the Anthrax BioThreat Alert Test Strip, why is it advertised as 100% accurate?

In order to claim 100% accuracy, it would be necessary to test every known substance on the strip. Since this is impossible as a practical matter, accuracy is determined from statistical calculations based upon the number of substances actually tested. No antibody-based test can ever be claimed to be 100% accurate.

### 3. How does a screening test compare to a confirmatory test?

A screening test provides a preliminary test result that has some degree of uncertainty. A confirmatory test result has such a high degree of certainty that is assumed to be 100% accurate. Screening tests are typically used in situations where one generally expects to find negative results, so the majority of unknown test samples can be discounted more easily, quickly and cost-effectively. The small proportion of samples giving positive results is then subjected to a more accurate confirmatory test, polymerase chain reaction (PCR) or standard microbiological assays.

#### 4. Are the *BioThreat Alert* Test Strips the same as SMART® Tickets?

No. *BioThreat Alert* Test Strips are completely different from the SMART® Ticket, employ different technology and are not manufactured by the same company. *BioThreat Alert* Test Strips utilize a lateral flow method and represent technology developed after the Gulf War to address the concerns raised by the high false-positive rates observed in earlier rapid test products.

#### 5. What is the shelf-life of the *BioThreat Alert* test strips?

Stored as labeled (15°- 30°C), our strips are warranted for at least 1 year from their manufacture date.

#### 6. Why is it so important not to open the *BioThreat Alert* Test Strip pouches until they are ready to be used?

Environmental moisture (water or humidity) can quickly degrade the *BioThreat Alert* Test Strips. The *BioThreat Alert* Test Strips are packaged individually and sealed at the factory. Although each pouch also contains a silica packet to absorb residual moisture, damage or punctures to the individual pouch will permit moisture to get into the *BioThreat Alert* Test Strip. Moisture leakage can quickly lead to degradation of the biochemical components of the *BioThreat Alert* Test Strip.

#### 7. Can I use the *BioThreat Alert* Test Strips beyond their expiration date?

Using the *BioThreat Alert* Test Strips beyond their expiration date is not recommended. Extended long-term storage testing helps determine the shelf life of the *BioThreat Alert* Test Strips. The shelf life is determined by results of these storage experiments under varied conditions. Eventually, the *BioThreat Alert* Test Strips will degrade, even if stored according to our recommendations. The actual degradation time will vary from by location due to environmental conditions. To ensure accurate test results, users must replace their *BioThreat Alert* Test Strips by the expiration dates.

#### 8. Why use the *Guardian Reader* with the *BioThreat Alert* Test Strips?

The *Guardian Reader* is recommended for the evaluation of all *BioThreat Alert* Test Strips. *BioThreat Alert* Test Strips give a visual indication of positive or negative results within 15 minutes after adding the sample. The user can inspect the *BioThreat Alert* Test Strip and make a subjective judgment of the presence or absence of the visual indicator. The *Guardian Reader* provides the added assurance of an objective analysis of the visual indicator while also providing documentation, data storage and chain of custody evidence for each test result. In addition, under low light or high stress conditions, the *Guardian Reader* relieves the user from the added pressure of making such subjective evaluations in the field. Finally, embedded radio frequency identification (RFID) technology provides automatic data backup for all tests. To summarize, the *Guardian Reader* provides an objective, quantitative result for each test strip, maximizing the sensitivity of the test while minimizing the probability of user error and misinterpretation.

#### 9. What kind of manufacturing quality control procedures are used for Alexeter products?

Both the *BioThreat Alert* Test Strips and the *Guardian Reader System* are manufactured under the same quality assurance practices observed by the medical products industry. Although we are not marketing medical devices, our manufacturing plants are compliant with both Food and Drug Administration (FDA) and ISO-9002 manufacturing guidelines. Compliance with these stringent quality assurance procedures ensures that our products will always meet or exceed the highest applicable standards.

#### 10. What if my *Guardian Reader* becomes contaminated?

The likelihood of cross-contamination of the *Guardian Reader* is minimal if basic care is taken in adding samples to *BioThreat Alert* Test Strips. However, it is our intention to ensure safety and confidence in our equipment. At the customer's request, Alexeter will replace at no cost, any *Guardian Reader* that comes in contact with confirmed positive samples for any biological agent.