Anthrax Rapid Test

Cat No. S031-04

INTENDED USE

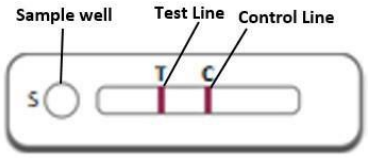
Sensit Athrax Rapid Test Kit for Anthrax Detection is an immunoassay designed for the qualitative detection of *Bacillus anthracis* antigens in human
Sensit Anthrax Rapid Test is only intended for initial screening and reactive samples should be confirmed by a supplemental assay such as ELISA or widal test.

SUMMARY &TEST DESCRIPTION

Anthrax is a potentially fatal infectious disease caused by the bacterium *Bacillus anthracis*, which primarily affects animals but can also infect humans. In humans, anthrax can manifest in different forms, including cutaneous, inhalation, gastrointestinal, and in some rare cases, systemic (septicemic) anthrax. Early detection of *Bacillus anthracis* is critical for timely intervention and treatment, especially in the event of a suspected bioterrorism attack or an outbreak in high-risk areas. This rapid test kit uses gold nanoparticle-based lateral flow immunoassay technology to provide a fast, simple, and reliable method for detecting anthrax-specific antigens in human clinical samples. The test is designed to detect the presence of *Bacillus anthracis* antigens in a variety of sample types, including blood, skin lesions, respiratory secretions, and other bodily fluids.The test delivers qualitative results within 15 minutes and is intended for use by healthcare professionals in clinical and laboratory settings as a preliminary screening tool for anthrax infection. By using this test, healthcare providers can quickly identify individuals at risk of anthrax exposure, enabling them to take immediate action for diagnosis and treatment

TEST PRINCIPLE

The test operates on a lateral flow immunoassay principle. Gold nanoparticles conjugated with antibodies specific to *Bacillus anthracis* antigens are applied to the sample.. Basic components of each test strip includes: a) Conjugate pad which contains colloidal gold conjugate; b) a nitrocellulose membrane strip containing two lines T: anti-*Bacillus anthracis* antibody. C: Goat Anti Mouse antibody.



Test sample that is added to the sample well (S), with adequate amount of buffer migrates from the sample pad along the conjugate pad where *Bacillus anthracis* antigens present in the sample will bind to Colloidal Gold conjugate to form a complex. The sample then continues to migrate across the membrane until it reaches the capture zones where the complex accordingly will bind to the immobilized anti-*Bacillus anthracis* antibody (on test lines) producing a visible lines on the membrane. If the respective antibody is not present in the Sample, no reaction occurs in the capture zones and no test line is formed. The sample then migrates further along the strip until it reaches the control zone, where it produces another visible line on the membrane. This control line indicates that the sample has migrated across the membrane as intended.

STORAGE & STABILITY

Store the test kit between 2-30°C till the expiration date indicated on the pouch / carton. DO NOT FREEZE. Ensure that the test device is brought to room temperature before opening.

REAGENTS & MATERIALS PROVIDED

1. Each test pouch contains:
a. One test card and dropper
b. Desiccant
2. Assay Diluent- In dropper bottle
3. Instruction Leaflet

PRECAUTION & WARNING

1. Use within 10 minutes after opening pouch.
2. Do not touch result window.
3. Use only the buffer supplied along with the kit.
4. Do not mix components from different kits.
5. Use only for in-vitro diagnostic purpose.
6. Treat all specimens, used tests and other contaminated materials as infectious, and dispose accordingly.
7. Do not use with hemolytic, lipemic or bacterially contaminated specimen.
8. Do not use with specimen containing precipitates

SAMPLE PREPARATION

- Specimen: Blood, Serum,Swab

1. **Blood**:

Collect the whole blood using a syringe or vacutainer into a container containing anticoagulants such as heparin, EDTA or sodium citrate by venipuncture.

2. **Serum:**

Collect the whole blood using a syringe or vacutainer (NOT containing anticoagulants such as heparin, EDTA or sodium citrate) by venipuncture.Leave the syringe or vacutainer, preferably at an angle, to settle for 30 minutes. Once blood coagulates, centrifuge the blood to get serum specimen as supernatant.

3. **Swab Samples:**

Swabs can be collected from exudates or secretions of open lesions, sputum from expectorated phlegm in cases of inhalation anthrax, and nasopharyngeal or oropharyngeal areas if respiratory infection is suspected.

Add 10-12 drops of extraction buffer into the extraction tube provided (till the mark in the tube). Insert the swab into the assay diluent and agitate it sufficiently in order to ensure good sample extraction

If the specimen is not used for testing immediately, they should be refrigerated at 2~8°C.

For storage period longer than 5 days, freezing is recommended. Store at -20 0 C

The specimen should be brought to room temperature prior to use.

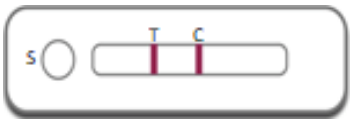
Treat the specimen as infectious and handle with standard biosafety measures.

TEST PROCEDURE

1. Take out the test card from the foil pouch and place it on a horizontal surface.
2. Add 35 µl of sample to the sample well "S".
3. When the sample is fully absorbed, add 1 drop of the diluent provided with the assay to the sample hole.
4. Wait for 10-15 minutes and interpret results. All results where control band does not appear are considered invalid.

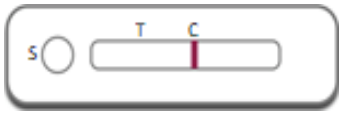
INTERPRETATION OF TEST RESULT

Positive: A clear pink control band ("C") and a detectable test band ("T") appear, indicating the presence of anthrax.

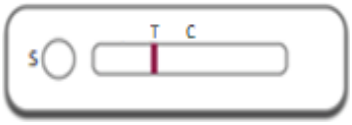


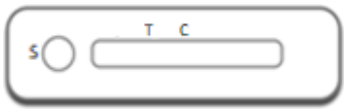
**Note: The intensity of the red color in the test region (T) will vary depending on the concentration of Anthrax present in the sample.*

Negative: A pink colored band appears only at control region ("C") indicating the absence of anthrax.



Invalid: If the control line fails to appear within the result window, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be retested.





References

1. Goepfert, P. A., & Hughes, M. A. (2004).*Anthrax: Diagnosis, Treatment, and Prophylaxis*.Clinical Infectious Diseases, 38(10), 1347-1354.
2. Rapid Detection of Bacillus anthracis Using a Lateral Flow Immunoassay and Antibody-Based Detection Methods.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in Anthrax Rapid Test for single-step detection of Anthrax are the most common signs appearing on medical devices and their packaging. They are explained in more detail in the European Standards EN 980: 2008 and INTERNATIONAL Standard ISO 15223-1:2016

Key to symbols used			
	Manufacturer		Expiration/use by date
	Do not reuse		Date of manufacture
	Consult IFU [Instructions For Use]	LOT	Batch code
	Temperature limitation 2-30°C	IVD	In Vitro diagnostic medical device
Σ X	Contains sufficient for 'X ' kits		Do not use if package is damaged
REF	Catalogue No		Keep dry

Please read the user manual carefully before operating to ensure proper use

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ubio Biotechnology Systems Pvt Ltd
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