

## In vitro Diagnostics

### INTENDED USE

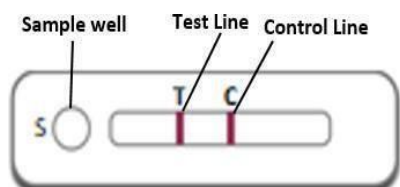
Sensit TB LAM Ag test is a rapid, point-of-care diagnostic tool designed to detect the lipoarabinomannan (LAM) antigen in urine samples, aiding in the diagnosis of active tuberculosis (TB), particularly among individuals living with HIV.

### SUMMARY & TEST DESCRIPTION

The Determine™ TB LAM Ag Test is primarily used to help diagnose active TB in **HIV-positive** individuals who show signs of TB or have **severe illness**. It is especially useful for those with advanced HIV who may have difficulty with other forms of TB diagnosis. This test is a valuable tool in the global effort to detect TB in HIV-infected individuals, providing early diagnosis and helping to guide appropriate treatment. The Determine™ TB LAM Ag Test is a rapid diagnostic test designed to detect lipoarabinomannan (LAM), an antigen found in the urine of individuals with active tuberculosis (TB).

### TEST DESCRIPTION & PRINCIPLE

The Determine™ TB LAM Ag Test is based on the immunochromatographic **assay** principle, which is a type of lateral flow immunoassay. This principle leverages antigen-antibody reactions to detect the presence of the lipoarabinomannan (LAM) antigen, which is a component of the Mycobacterium tuberculosis cell wall. LAM is released into the urine of individuals with active TB, especially those who are immunocompromised, such as people living with HIV.



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 TB LAM antibodies 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 will bind to the immobilized TB LAM recombinant antigen (on test line) producing a visible line on the membrane. If the respective antibodies are not present in the sample, no reaction occurs in the capture zone 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.

### MATERIALS PROVIDED

1. Each sealed in a foil pouch containing following items:
  - a. One Test card
  - b. Dropper
  - c. Desiccant
2. Assay Diluent- In dropper bottle
3. Instruction Leaflet

### 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.

### 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) Do not reuse the test device; each test can be used **ONLY SINGLE TIME**.
- 6) Use only for in-vitro diagnostic purpose.

### SAMPLE COLLECTION

#### Collect the Urine Sample:

- Collect the **urine sample** from the patient in a clean container.
- Ensure the sample is well-mixed before using it in the test. It is recommended to use **fresh urine** for the test, ideally collected within the last **2 hours**.

*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°C*

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

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

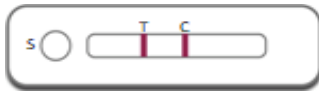
### TEST PROCEDURE

1. Remove the Determine™ TB LAM Ag Test device from its packaging and place it on a flat, clean surface.
2. ☒ The test device is pre-assembled and ready for use.
3. Using a dropper or the sample application device provided in the test kit, place 3 drops of urine onto the sample pad of the test device.
4. Avoid touching the sample pad with the dropper or any other object.
5. Start a timer immediately after applying the urine sample to the device.
6. Wait for 25 minutes for the test to complete. Do not read results after 30 minutes, as the test may become invalid after this time.

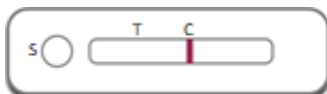
## INTERPRETATION OF TEST RESULT

(IMPORTANT NOTE: INTERPRET THE RESULTS WITH RESPECT TO THE WRITINGS 'C' & 'T' ON THE DEVICE AS SHOWN BELOW.

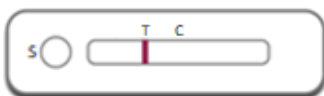
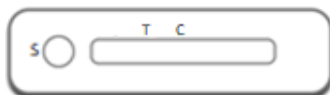
**Positive:** Color bands at position C and T. TB LAM is present in the sample



**Negative:** Color band at position C. TB LAM is not present in the sample















**Invalid:** Color band at C does not appear




## DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in TB LAM Rapid Test for single-step detection of TB LAM 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]		Batch code
	Temperature limitation 2-30°C		In Vitro diagnostic medical device
	Contains sufficient for 'X' kits		Do not use if package is damaged
	Catalogue No		Keep dry

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

Manufactured by,

 ubio Biotechnology Systems Pvt Ltd  
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Kalamassery, Cochin, Kerala, India 683503  
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