

# Listeria antibody Rapid Test Kit

Cat No. S044-01

## In vitro Diagnostics

### INTENDED USE

Sensit listeria antibody Rapid Test kit using gold is a diagnostic tool for the rapid detection of Listeria antibodies in human serum or plasma. It is designed for use in clinical settings to aid in the detection of Listeria infections

### SUMMARY & TEST DESCRIPTION

Listeria monocytogenes is a pathogenic bacterium that can cause listeriosis, a serious infection that primarily affects vulnerable groups such as pregnant women, neonates, the elderly, and those with weakened immune systems. Early diagnosis and treatment are essential to reduce the risks associated with this infection. The Listeria Antibody Rapid Test using Gold is an immunoassay designed to detect antibodies specific to Listeria monocytogenes in human serum or plasma samples. By utilizing colloidal gold method, this test provides quick and reliable results, typically within 15 minutes, without the need for specialized laboratory equipment. It works by detecting the presence of antibodies that the body produces in response to Listeria infection.

### TEST DESCRIPTION & PRINCIPLE

Sensit Listeria Antibody Rapid Test using Gold is based on the principle of lateral flow immunoassay, which utilizes the specific interaction between Listeria antibodies in the sample and antigens on the test device. When a sample (serum or plasma) is applied to the test device, it migrates along the membrane via capillary action. If the sample contains antibodies specific to *Listeria monocytogenes*, these antibodies will bind to the pre-coated Listeria antigens, which are conjugated to colloidal gold particles. As the sample continues to migrate, this antigen-antibody binding forms a visible colored line at the test region, indicating the presence of Listeria antibodies. A separate control line appears regardless of the sample's composition, ensuring the test is functioning correctly. This simple yet effective immunochromatographic process allows for rapid detection of Listeria antibodies, providing results within minutes.

### MATERIALS PROVIDED

1. Each test pouch contains:
  - a) One test card and dropper
  - b) Desiccant
2. 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

- a) Use within 10 minutes after opening pouch.
- b) Do not touch result window.
- c) Do not reuse test kit.
- d) Do not use test kit beyond expiry date.
- e) Use only for in-vitro diagnostic purpose.

### SAMPLE COLLECTION

#### Specimen: Blood (serum/plasma)

- Collect 2–5 mL blood in serum or plasma tubes, centrifuge at 1500-2000rpm for 10-15 min, and store at 2–8°C (48 hrs) or -20°C (long-term). Blood analysis is the gold standard in monitoring the physiological state of individuals.

Note:

- 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

- Take out the test card from the foil pouch and place it on a horizontal surface.
- Add 3 drops of the specimen to the Sample well "S"
- Wait for 10 minutes and interpret the result. The result is considered invalid after 15 minutes.

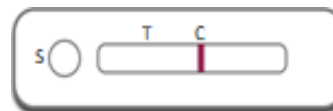
### INTERPRETATION OF TEST RESULT

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

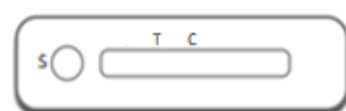
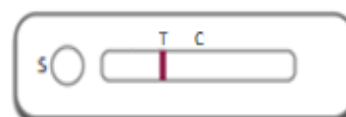


*\*Note: The intensity of the red color in the test region (T) will vary depending on the concentration of listeria present in the sample.*

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



**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.















## LIMITATIONS

1. This test detects antibodies against *Listeria monocytogenes*, which may not be present in the early stages of infection. A negative result does not necessarily rule out a current infection, especially in asymptomatic individuals or those with weak immune responses.
2. The test may produce false positive results due to cross-reactivity with other bacterial infections or conditions that share similar antibody profiles.
3. The accuracy of the test may be affected by improper sample collection, contamination, or improper handling and storage of the specimen. It is essential to follow the proper guidelines for specimen collection and handling.
4. The test is intended for the detection of *Listeria* antibodies in human serum or plasma only. It should not be used with other types of specimens.
5. This test detects antibodies rather than the bacteria itself. It is not suitable for detecting active infections in the absence of antibodies.
6. Testing too early in the course of infection may result in a false negative, as antibodies may not have developed to detectable levels.
7. Results should always be interpreted in conjunction with other clinical findings and diagnostic tests. A positive result should be confirmed with further laboratory testing.


## DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in *Listeria* Antibody Rapid Test Kit for single-step detection of *Listeria* 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  
Plot # 15A, Biotechnology Zone  
Kalamassery, Cochin, Kerala, India 683503  
Ph:, +91-484-2970043  
<http://www.ubio.in>  
e-mail: [contact@ubio.co.in](mailto:contact@ubio.co.in)