## Tularemia Rapid Test

**Cat. No.:** DTS745  
**Pkg. Size:** 10 Tests

### Intended use

Immunochromatographic test for the qualitative detection of total antibodies against *Francisella tularensis* in human serum/plasma.

### Kit Features

The test is accomplished in minutes with the help of materials and equipment commonly found in any laboratory and can be read visually. We recommend to read carefully the “Precautions” section.

### General Description

*Francisella tularensis* is a pathogenic species of Gram-negative bacteria and the causative agent of tularemia or rabbit fever. It is a fastidious, facultative intracellular bacterium which requires cysteine for growth. Due to its ease of spread by aerosol and high virulence, *F. tularensis* is classified as a Class A Select Agent by the U.S. government, along with other potential agents of bioterrorism such as *Yersinia pestis*, *Smallpox* and the Filoviruses.

### Principle Of The Test

When the sample is added into the well of the cassette, the colloidal gold is solubilized and the first immunological reaction between the specific antibodies of the serum/plasma and the protein coupled to the gold particles takes place. These complexes move along the membrane to the reaction line (test line), and a colored band will appear if the analyte to be detected is present in the sample. Each strip contains a control line for the validation of the assay. This line has to appear always even if the sample is negative.

### Reagents And Materials Provided

1. **CD TULAREMIA CASSETTE:** 10 cassettes for the specific detection of total antibodies against *Francisella tularensis*.
2. **CD TULAREMIA DEVELOPER SOLUTION:** 1.5 ml of buffered solution, containing sodium azide.

### Materials Required But Not Supplied

1. Automatic micropipette and the corresponding tips
2. Chronometer

### Storage

Store at room temperature or refrigerated, 2-30°C. **DO NOT FREEZE.** Do not use the kit reagents beyond the expiry date. This will be valid only if reagents are capped and stored at 2-30°C.

### Specimen Collection And Preparation

Blood should be collected aseptically using venipuncture techniques by qualified personnel. Use of sterile or aseptic techniques will preserve the integrity of the specimen. Serum samples are to be refrigerated (2-8°C) upon collection or frozen (-20°C) if the test cannot be performed within 7 days. Samples should not be repeatedly frozen and thawed. Do not use hyperlipemic, hemolyzed or contaminated sera. Samples containing particles should be clarified by centrifugation.
Reagent Preparation

All reagents supplied are ready to use.

Reagent Stability

1. CD CASSETTE: Once opened, use in the next hour.
2. Rest of the components: Store at 2-30°C and use until expiration date.
3. The kit is stable until the expiration date at 2-30°C.
4. Handle reagents in aseptic conditions to avoid microbial contaminations.
5. CD, S.L. does not accept responsibility for the mishandling of the reagents included in the kit.

Assay Procedure

1. Bring all reagents to room temperature before use (approximately 1 hour), without removing the cassettes from the pouches.
2. Open the pouch and put the cassette 1 on a flat surface.
3. Add 20 μl of sample into the well with an automatic micropipette. Let the drop be absorbed.
4. Add 2 drops of developer solution 2 onto the well.
5. The result must be read within 15-30 minutes.

Discard any reading made after 30 minutes.

Quality Control

Each batch is subjected to internal quality control testing before releasing, complying with highly strict specifications. Final quality control results for each particular lot are available.

Interpretation of Results

In order to perform the reading of the test and to determine the positivity of the samples, the intensity card included in the kit should be used. 4 levels of color intensity ranging from 0.5 to 3 can be read. When the intensity is lower than 0.5, the result is considered negative. When the intensity is higher than or equal to 0.5, the result is considered positive.

If the sample contains antibodies against Francisella tularensis, a coloured line will appear in the corresponding place. The control line must be always positive and legible if the test has been performed correctly. If this line does not appear, the test must be considered invalid.
Sensitivity and Specificity

256 samples were assayed against an available microagglutination kit. The results were as follows:

Sensitivity(%) 99.13; Specificity(%) 98.58.

Precision

INTRA-ASSAY PRECISION:
2 samples (one positive close to the detection limit and one negative) were tested 5 times in a single assay performed by the same operator in essentially unchanged conditions.
The same results were observed in all the assays.

INTER-ASSAY PRECISION:
2 samples (one positive close to the detection limit and one negative) were individually tested on 3 consecutive days by 2 different operators.
The same results were observed in all the assays.

Cross-Reactivity and Interferences
8 samples known to be positive for other specimens (cytomegalovirus, Toxoplasma gondii and Epstein-Barr virus) were assayed. 8 samples known to be positive for rheumatoid factor were assayed. No false positive results were obtained.

**Precautions**

1. For professional use only.
2. Use kit components only. Do not exchange CD CASSETTES and CD DEVELOPER SOLUTION between lots and kits.
3. Specimens should be handled as in the case of infectious samples using safety laboratory procedures.
4. Wear protective disposable gloves, laboratory coats and eye protection when handling specimens. Wash hands thoroughly after manipulating samples.
5. Do not use the kit after expiration date.
6. Dispose of unused reagents and waste in accordance with all applicable regulations.
7. Reagents in this kit could include genetic material or substances of animal and/or human origin. Although that material is not infectious, it should be handled as potentially infectious. All material should be handled and disposed as potentially infectious. Observe the local regulations for waste disposal.
8. The developer solution contains sodium azide. Sodium azide may react with metal plumbing, forming explosive components. Upon disposal, flush with plenty of water. Observe the local regulations for chemical waste disposal.
9. If the kit or its components (cassettes or developer solution) are stored in the refrigerator, please bring them at room temperature before use.
10. The cassettes are stable in their closed pouch until the expiry date indicated in the label. Do not open until you are ready to perform a test.
11. Several tests can be performed at the same time.
12. Do not let that the tip of the developer solution bottle touch the sample well in order to prevent contaminations.
13. A good performance of the test depends on the correct size of the drops of developer solution. For this purpose, push the dropper smoothly, allowing the air to pass through into the bottle between each two samples.
14. Avoid the use of samples subjected to repeated freezing-thawing cycles as well as hemolyzed samples. Both can produce erroneous results (signal decrease) or reading failures (lack of visibility).

**Limitations**

1. This kit is intended to be used with human plasma/serum.
2. The user of this kit is advised to carefully read and understand the package insert. Strict adherence to the protocol is necessary to obtain reliable test results.
3. The test provides qualitative results. No correlation can be drawn between the magnitude of a positive result and the titer of antibodies in the sample.

**REFERENCES**
