Tetanus Rapid Test Cassette (Whole Blood/Serum/Plasma)

Package Insert

REF ITE-402 | English

A rapid test for the qualitative detection of antibodies to tetanus toxin in whole blood, serum or plasma.

For professional in vitro diagnostic use only.

【INTENTED USE】

The Tetanus Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibodies to Tetanus toxin in whole blood, serum, or plasma to aid in the diagnosis of Tetanus toxin infection.

【SUMMARY】

Clostridium tetani is a bacterium that causes tetanus in humans. *Clostridium tetani* ate Gram-positive, spore-forming rods that are anaerobic. If they enter the body through a wound, they can multiply and produce a toxin that affects the nerves and controls the activity of muscles. Toxin of *Clostridium tetani* binds to membranes of peripheric nervous cells and inhibits the release of neurotransmitters.

Antibodies to tetanus toxin are produced in the human by the injection of chemically inactivated tetanus toxin (tetanus toxoid). Immunization is the best way to prevent *C. Tetani* infections in children and adults. Moreover, injection of specific and purified anti tetanus toxin IgG is used in order to refrain toxin action during an acute infection.[1,2,3,4]

It is sometimes better to know the level of anti-tetanus toxin antibodies in a patient, to evaluate their immune status, in order to determine the necessity of a complementary vaccination which would assure immunity towards tetanus toxin.

In emergency situations, it is important for the clinician to know the immune status in order to decide on the correct anti-tetanus prophylaxis for high risk patients (deep wounds).[5,6,7]

【PRINCIPLE】

The Tetanus Rapid Test is a qualitative membrane based immunoassay for the detection of Tetanus Toxin antibodies in whole blood, serum, or plasma. In this test procedure, anti-human IgG is coated in test line region. During testing the specimen reacts with tetanus antigen-coated particles in the test. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgG in test line region. If the specimen contains tetanus antibodies to tetanus, a colored line will appear in test line region. If the specimen does not contain tetanus antibodies, no colored line will appear in either of the test line region, indicating negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The test contains tetanus toxoid antigen coated particles and anti-human IgG coated on the membrane.

【PRECAUTIONS】

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- The used test should be discarded according to local regulations.
- Humidity and temperature may adversely affect results.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

The Tetanus Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood, serum, or plasma.

To collect Venipuncture Whole Blood specimens:

- Collect anti-coagulated blood specimen (sodium or lithium heparin, potassium or sodium EDTA, sodium oxalate, sodium citrate) following standard laboratory procedures.

To collect serum/plasma Specimens:

- Collect whole blood by venipuncture
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.

Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C.Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly. If specimens are to be shipped, they should be packed in compliance with local regulations for transportation of etiologic agents.

【MATERIALS】

Materials provided

• Test cassettes • Droppers • Buffer • Package insert

Materials required but not provided

• Specimen collection containers • Centrifuge • Timer

【DIRECTIONS FOR USE】

Allow the test, specimen, buffer to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. Place the cassette on a clean and level surface.

For **Serum or Plasma** specimen:

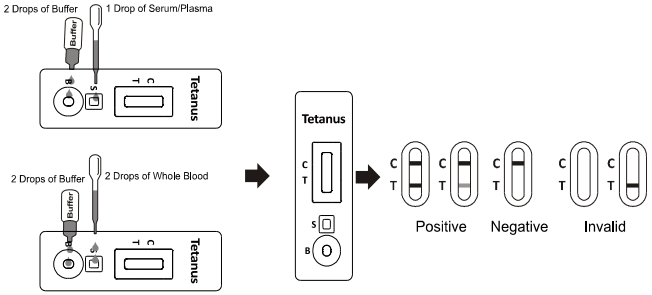
- Hold the dropper vertically and transfer **1 drop of serum or plasma** (approximately 25 μL) to the specimen well (S) of test cassette, then **add 2 drops of buffer** (approximately 80μL) to the buffer well (B), , and start the timer. See illustration below.

For **Venipuncture Whole Blood** specimen:

- Hold the dropper vertically and transfer **2 drops of whole blood** (approximately 50 μL) to the specimen well (S), then **add 2 drops of buffer** (approximately 80 μL) to the buffer well (B), and start the timer. See illustration below.

3. Wait for the colored line(s) to appear. **Read results at 15 minutes.** Do not interpret the result after 20 minutes.

Note: It is suggested not to use the buffer, beyond 6 months after opening the vial.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

POSITIVE:* Two colored lines appear. One colored line should be in the control region (C) and another colored line should be in the test region (T).

***NOTE**: The intensity of the color in the test line region (T) will vary depending on the concentration of Tetanus antibody present in the specimen. Therefore, any shade of color in the test region (T) should be considered positive.

NEGATIVE: One colored line appears in the control region (C). No colored line appears in the test region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

A procedural control is included in the test. A colored line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

【LIMITATIONS】

1. The Tetanus Rapid Test Cassette (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. The test should be used for the detection of Tetanus antibodies in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in Tetanus antibody concentration can be determined by this qualitative test.
2. The Tetanus Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of Tetanus antibodies in the specimen and should not be used as the sole criteria for the diagnosis of Tetanus infection.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of Tetanus infection.
5. The hematocrit of the whole blood should be between 25% and 65%.

【PERFORMANCE CHARACTERISTICS】

Clinical Sensitivity, Specificity and Accuracy

A total of 155 specimens were tested by Tetanus Rapid Test Cassette (Whole Blood/Serum/Plasma) and Tetanus other rapid test, both of them could detect 70 positive results and 85 negative results, sensitivity of Tetanus Rapid Test Cassette was 98.6%, specificity of the test was 98.8%.

Method		Tetanus Other rapid Test		Total Results
Tetanus Rapid Test Cassette	Results	Positive	Negative	
	Positive	69	1	70
	Negative	1	84	85
Total Results		70	85	155

Relative Sensitivity: 98.6% (95%CI*: 92.3%-99.9%) *Confidence Interval
Relatively Specificity: 98.8% (95%CI*: 93.6%-99.9%)
Accuracy: 98.7% (95%CI*: 95.4%-99.8%)

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of four specimens: a negative, a low positive, a medium positive and a high positive. The negative, low positive, medium positive and high positive values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the same four specimens: a negative, a low positive, a medium positive and a high positive. Three different lots of the Tetanus Rapid Test Cassette (Whole Blood/Serum/Plasma) have been tested using negative, low positive, medium positive and high positive specimens. The specimens were correctly identified >99% of the time.

Sensitivity

The detection level determination of Tetanus Rapid Test could detect out antibody to tetanus as low as 0.1 IU/mL.

Hook Effect

No high-dose hook effect was detected at the concentration up to 45 IU/mL.

Cross-reactivity

The following organisms were found negative when tested with the Tetanus Rapid Test Cassette. (Whole Blood/Serum/Plasma).

HIV	*Rubella virus*	*Hepatitis A virus IgG*
Hepatitis B virus	*Pertussis IgG*	*Varicella zoster virus IgG*
Treponema pallidum IgG	*EB virus IgG*	*Mycoplasma pneumoniae IgG*
Cytomegalovirus IgG	*Herpes simplex virus IgG*	*Toxoplasma gondii IgG*
Diphtheria toxoid IgG	*RF*	

No cross-reactivity was observed, indicating that the Tetanus Rapid Test has a high degree of specificity for antibodies to tetanus toxin.

Interfering Substances

The Tetanus Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested for possible interference from visibly hemolyzed and lipemic specimens, as well as serum specimens containing high bilirubin levels. In addition, no interference was observed in specimens containing up to 1,000 mg/dL hemoglobin; up to 1,000 mg/dL bilirubin; and up to 2,000 mg/dL human serum albumin.

【BIBLIOGRAPHY】

1. Kennedy, J.W., Carey, R.N., Coolen, R.B., et al., Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline (EP5-A). Villanova, PA: The National Committee for Clinical Laboratory Standards, 19(2):1999.
2. Powers, D.M., Glick, M.R., et al., Interference Testing in Clinical Chemistry; Approved Guideline (EP7-P). Villanova, PA: The National Committee for Clinical Laboratory Standards, 22(27): 1986.
3. Passey, R.B., Bee, D.E., Caffo, A., et al., Evaluation of the Linearity of Quantitative Analytical Methods (EP6-A). Villanova, PA: The National Committee for Clinical Laboratory Standards, 23(16):1986.
4. Wang, A.S., Burns, G.F., Kronborg, I.J. and Mackay, I.R., Detection of antibodies to tetanus toxoid: comparison of a direct hemagglutination method with a radioimmunoassay. Journal of Clinical Pathology, 35: 1138-1141 (1982).
5. Kiessig, S.T., Hentschel, C., Jahn, S., Mehl, M., Starke, R. and Porstmann, T., A solid-phase enzyme immunoassay for the detection of tetanus toxin using human and murine monoclonal antibodies. Journal of Basic Microbiology, 31: 135-140 (1991).
6. Gergen, P.J., McQuillan, G.M., Kiely, M., Ezzati-Rice, T.M., Sutter, R.W. and Virella, G., A Population-Based Serologic Survey of Immunity to Tetanus in the United States. The New England Journal of Medicine, 332(12): 761-766 (1995).
7. Simonsen, O., Bentzon, M.W. and Heron, I., ELISA for the routine determination of antitoxic immunity to tetanus. Journal of Biological Standardization, 14: 231-239 (1986).

Index of Symbols

⚠	Caution	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by	2	Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged		Manufacturer		Consult Instructions for Use

Hangzhou AllTest Biotech Co.,Ltd.
#550,Yinhai Street
Hangzhou Economic & Technological Development Area
Hangzhou, 310018 P.R. China
Web: www.alltests.com.cn Email: info@alltests.com.cn

EC REP
MedNet GmbH
Borkstrasse 10
48163 Muenster
Germany

Number: 145130802
Effective date: 2022-03-23