SCREEN 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.

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).

【PRINCIPLE】

The Tetanus Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative membrane based immunoassay for the detection of Tetanus Toxin antibodies in whole blood, serum, or plasma. In this test procedure, purified tetanus toxoid (a non-pathogenic derivative of tetanus toxin) is immobilized in the test line region of the test. After specimen is added to the specimen well of the device, it reacts with Tetanus toxoid coated particles in the test. This mixture migrates chromatographically along the length of the test and interacts with the purified tetanus toxoid. If the specimen contains tetanus antibodies, a colored line will appear in the test line region indicating a positive result. If the specimen does not contain tetanus antibodies, a colored line will not appear in this region indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The test contains tetanus toxoid coated particles and purified tetanus toxoid 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 can 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 Fingerstick Whole Blood Specimens:

- Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
- Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Add the Fingerstick Whole Blood specimen to the test cassette by using a dropper or micropipette measuring 25 ul. The dropper provided with the test dispenses approximately 25 ul in one drop even if more blood is aspirated in the dropper.

Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods.

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 federal regulations for transportation of etiologic agents.

【MATERIALS】

Materials provided

• Test cassettes • Droppers • Buffer • Package insert

Materials required but not provided

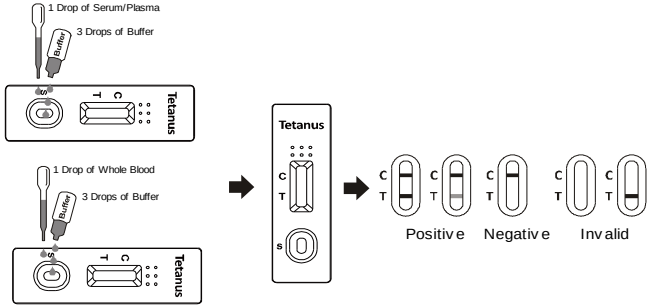
• Specimen collection containers • Centrifuge
• Lancets (for fingerstick whole blood only) • Timer
• Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

【DIRECTIONS FOR USE】

Allow the test, specimen, buffer and/or controls 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 of test cassette, then **add 3 drops of buffer** (approximately 120ul), and start the timer. See illustration below.

   For **Venipuncture Whole Blood** specimen:
   - Hold the dropper vertically and transfer **1 drop of whole blood** (approximately 25 μL) to the specimen well, then **add 3 drops of buffer** (approximately120 μL), and start the timer. See illustration below..
3. Wait for the colored line(s) to appear. **Read results at 10 minutes.** Do not interpret the result after 20 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

POSITIVE:* Two distinct 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 apparent 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. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

【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.

【EXPECTED VALUES】

The Tetanus Rapid Test Cassette (Whole Blood/Serum/Plasma) has been compared with a lead Tetanus ELISA test demonstrating an overall accuracy of 97.8%.

【PERFORMANCE CHARACTERISTICS】

Clinical Sensitivity, Specificity and Accuracy

A total of 596 specimens were tested by Tetanus Rapid Test Cassette (Whole Blood/Serum/Plasma) and Tetanus ELISA test, both of them could detect 128 positive results and 455 negative results, sensitivity of Tetanus Rapid Test Cassette was 94.1%, specificity of the test was 98.9%.

Sensitivity and Specificity

Method		Tetanus EIA		Total Results
Tetanus Rapid Test Cassette	Results	Positive	Negative	
	Positive	128	5	133
	Negative	8	455	463
Total Results		136	460	596

Relative Sensitivity: 94.1% (95%CI*: 88.7%-97.4%) *Confidence Interval
Relatively Specificity: 98.9% (95%CI*: 97.5%-99.6%)
Accuracy: 97.8% (95%CI*: 96.3%-98.8%)

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

Cross-reactivity

Sera containing known amounts of antibodies to Tetanus have been tested with Hepatitis A, B, C, E, HIV and Syphilis. No cross-reactivity was observed, indicating that the Tetanus Rapid Test Cassette (Whole Blood/Serum/Plasma) 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.

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Index of Symbols

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

SCREEN ITALIA S.r.l.
Via dell'Artigianato, 16
06089 - Torgiano - Perugia - Italia
www.screenitalia.it info@screenitalia.it

CE

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