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

Package Insert

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

[INTENDED USE]

The Tetanus Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunassay 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]

Clodstridium tetani is a bacterium that causes tetanus in human. Clodstridium tetani enter Gram-positive spore-forming rods that are anaerobic bacteria. When they enter the body through wounds, they may multiply and produce a toxin that affects the nerves and controls the activity of muscles. Toxin of Clodstridium tetani binds with the nervous cells of peripheral nerves and inhibits the release of neurotransmitters. Antibodies to tetanus toxin are produced in the human by the injection of chemically inactivated tetanus toxoid (Tetanus toxin). 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 reinoculate toxin during an acute infection. It is sometimes better to know the level of anti tetanus antibodies in a patient, to evaluate their immunity 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 immunity 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 immunassay 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 area. The immuno chromatography 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 always appears in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

[STORAGE AND STABILITY]

Store as packaged in the sealed pouch at room temperature or refrigerated (2-8°C) if the test is to be run within 2 days of opening the sealed pouch and use it as soon as possible. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and place it on a clean, flat surface. Do not use if the test cassette has been frozen. Once opened, the test cassette should not be exposed to light. Each test kit contains 25 test cassettes... The test cassette consists of a plastic cassette containing the following elements (Please refer to the illustration above):

- **Buffer**: 1 Drop of Buffer (approximately 20μl)
- **Whole Blood Specimen**: 3 Drops of Whole Blood (approximately 30μl) to 2 ml of Buffer
- **Serum or Plasma Specimen**: 1 Drop of Serum/Plasma
- **Tetanus Rapid Test Cassette**: 1 Drop of Tetanus Rapid Test Cassette

**INTERPRETATION OF RESULTS**

**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 possible 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 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**

- 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. The quantitative value of increase in Tetanus antibody concentration can be determined by this qualitative test.
- 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.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- 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 ELIISA test demonstrating an overall accuracy of 94.6%.

**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 whom could detect 138 positive results and 458 negative results. Sensitivity of Tetanus Rapid Test Cassette was 94.1%, specificity of the test was 95.8%.

**Accuracy**

- **Clinical Sensitivity**: 94.1% (95%CI: 93.5%-94.7%)
- **Specificity**: 95.8% (95%CI: 95.3%-96.8%)
- **Cross-reactivity**: 460
- **Precision**

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 four different batches and four independent tests 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 EBV. No cross-reactivity was observed. Immuno chromatography of 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 various hemolyzed and impiscic 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 of bilirubin, and up to 2,000 mg/dL of serum albumin.

[REFERENCES]


[SCREEN ITALIA Srl Via Volumnia, 40/b 06135 Ponte San Giovanni - Perugia - Italia www.screenitalia.it info@screenitalia.it]

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