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CE

"See Now" Salmonella (typhoid) IgG/IgM Test
Serum/ Plasma/ Whole Blood
For in vitro Diagnosis Use
Product Code: SN 9.2

INTENDED USE

"See Now" Salmonella (Typhoid fever) Antibody Test is a colloidal gold-antibody complex immunoassay for *in vitro* qualitative determination of anti-Salmonella Typhi IgG and IgM antibodies in human serum, plasma or whole blood. It is intended for professional use.
This assay provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the results of the test.

SUMMARY AND EXPLANATION OF THE TEST

Typhoid fever is caused by S. typhi, a Gram-negative bacterium. World-wide an estimated 17 million cases and 600,000 associated deaths occur annually1. Patients who are infected with HIV are at significantly increased risk of clinical infection with S. typhi2.
Evidence of H. pylori infection also presents an increase risk of acquiring typhoid fever. 1-5% of patients become chronic carrier harboring S. typhi in the gallbladder.

Materials Provided

Pouch Contents: Cassette, Sample Dropper, Desiccant, Test instruction, buffer.

Materials needed but not provided

- Clean, specimen collection container.
- Clock or timer.

SPECIMEN COLLECTION & PREPARATION

- Collect blood in a tube without anticoagulant for serum samples and allow to clot.
- For whole blood / plasma samples, collect the blood in a tube containing anticoagulant.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods.

TEST PROCEDURE

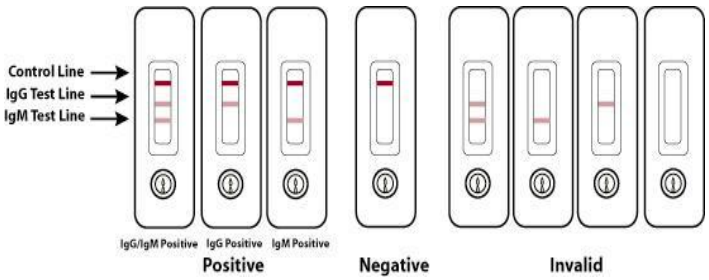
1. Remove the testing device from the sealed pouch by tearing at the notch. Then place the testing device on a leveled surface.
2. Holding the sample dropper vertically add 2 drops (around 8**0µL)** of specimen into the sample well, then 1 drop , around **40µL** of buffer.
3. Read the result at 10-15 minutes. Ensure that the background of the test area is white before interpreting the result.

INTERPRETATION OF RESULTS

Negative: Only one pink color band appears on the control region. There is no apparent color band on the test region.

Positive: Distinct pink color bands appear at the control and either/both IgG and IgM test line regions.

Invalid: A total absence of color in both regions and no colored line appears in the control (C) region is an indication of procedure error and/or test reagent deterioration. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



LIMITATIONS

This product is designed for in vitro diagnostic use only.
There is always a possibility that false results will occur due to factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

STORAGE AND STABILITY

The test kit can be stored at temperatures between 4 to 30ºC in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat.

PRECAUTION

1. For in vitro diagnostic use only.
2. Do not use test kit beyond expiry date.
3. The test device should not be reused.
4. *The instructions for use and reading of the test must be followed exactly in order for the test to perform properly.*
5. *Standard guidelines for handling infection agents and chemical reagents should be observed throughout all procedures.*

Performance Characteristics

Salmonella IgM test

Sensitivity: 91.50%
Specificity: 99.30%
Accuracy: 98.50%

Salmonella IgG test

Sensitivity: 92.90%
Specificity: 99.30%
Accuracy: 99.00%