TYPHOID IgG/IgM RAPID TEST

INTENDED USE

Nuvision Typhoid IgG/IgM Test is a rapid immunochromatographic assay for the detection of IgG and IgM antibodies against Salmonella typhi using human Serum/Plasma/Whole blood samples. It is intended for professional use as a tool in the diagnosis and controlling the treatment of severe typhi infection and sepsis.

SUMMARY

Salmonella typhi (S. typhi) is a gram-negative bacterium and it is the causative agent of typhoid fever. Typhoid fever can be diagnosed by isolation of S. typhi from blood, urine, or stool but this method requires laboratory equipments, technical training and time- consuming procedures. Widal test is used for sero diagnosis of typhoid fever but it also has many limitations on the interpretation. Nuvision Typhoid IgG/IgM is a simple and rapid laboratory test, which can detect antibodies against S. typhi (not to S. paratyphi species) in whole blood.

PRINCIPLE OF THE ASSAY

The nitrocellulose membrane of the kit is immobilized with anti- human IgM (test line M), anti-human IgG (test line G), and goat anti- mouse antibodies (control line C). And also, S. typhi conjugated to the colloidal gold particles, respectively. These conjugates are placed on a polyester or glass pad as conjugate pad. When the sample is dropped into the sample well on the device, the solubilized conjugate sample come into contact with the antibodies that immobilized onto the nitrocellulose. If the sample contains antibodies against S. typhi the result is visible as red line within ~20 minutes in the test line "M" (IgM) and/or in test line "G" (IgG) on the membrane. The solution continues to migrate to encounter a control reagent that binds a control conjugate, thereby producing another red control line.

PACKAGE CONTENTS

- 25 Test kits (pouches) per box
- Pouch contents: Test Cassette, Desiccant.
- Sample Dropper (25 Nos.)
- Buffer Solution (1 vial, 3mL/vial)
- 1 Test instruction per box

MATERIALS REQUIRED (BUT NOT PROVIDED)

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

WARNINGS AND PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not reuse.
- Do not use if the product seal or the packaging is compromised.
- Do not use, after the expiration date shown on the pouch.
- Do not mix and interchange different specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials and performing the assay.
- Wash hands thoroughly after finishing the test.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Clean up spills thoroughly with appropriate disinfectants.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
- Dispose of all specimens and used devices in a proper bio- hazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations.
- Keep out of children's reach.

SPECIMEN PREPARATION

- For serum samples, collect blood in a tube without anticoagulant and allow it to clot.
- For plasma samples, collect 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.
- Whole blood: whole blood should be collected over heparin, citrate, or EDTA. Mix the blood by inversion and use it to the test. If fingertip blood is used to the test, prick the finger and collect the blood by a capillary tube. And then, load the blood onto the sample well (S) of the test device.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods.
- The blood may be stored at 2°C to 8°C for up to three days if the tests cannot be performed immediately. Ensure that the blood samples are allowed to attain room temperature prior to use. Note: Hemolytic samples should not be used!

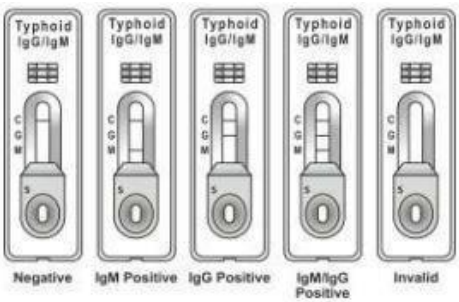
PROCEDURE

- Bring the kit components to room temperature before testing.
- Open the pouch and remove the Test. Once opened, the test must be used immediately.
- Label the test card with patient's identity.
- Hold the sample dropper vertically. Add one full drop (30 µL) of the specimen without air bubbles into the sample well that is marked with "S" on the testing device.
- Add 2 drops (80 µL) of buffer solution in the sample well.
- Read the results at the end of 15 minutes. A strong positive sample may show result earlier.

  Note:

  1. Some positive samples may show positive results before 15 minutes.
  2. DO NOT READ RESULTS AFTER 20 MINUTES. To avoid confusion, discard the test device after interpreting the results.

INTERPRETATION OF RESULTS



Negative

A pink colored band appears only at the control region (C), No band appears in Test region.

Positive

A clear pink control band (C) and a detectable test band (T) appears on their respective regions (G, M), indicating a positive result for Typhoid IgG/IgM.

Invalid

No visible band at the control region (C). Repeat with a new test device. If the test still fails, please contact the distributor with the lot number.

Note:

This test is designed for primary screening test of IgG and IgM antibodies against S.typhi (not to S.paratyphi species). Although this kit can provide fast and easy way to get a result, the testing can alone be used to be diagnose S. typhi antibodies and also the testing do not completely exclude the possibility of false positive or false negative result caused by various factors. So refer to the result of this kit and make a final decision with symptoms, other test results, and doctor's view, collectively. 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

- **Test device in the sealed pouch should be stored at 2°-30°C. Do not freeze the test device.**
- **If stored at 2°-8°C, ensure that the device is brought to room temperature before opening.**
- **The test device should be kept away from direct sunlight, moisture and heat.**
- **Do not expose the kit over 30°C.**

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity studies were carried out in-house on fresh as well as frozen samples, from low risk as well as high risk groups.

Typhoid IgG Samples	Positive	Negative	Total
Positive	17	01	18
Negative	01	107	108
Total	18	108	126

Relative Sensitivity: 94.4%, Relative Specificity: 99.0%, Overall agreement: 96.7%

Typhoid IgM Samples	Positive	Negative	Total
Positive	30	00	30
Negative	01	108	108
Total	31	108	139

Relative Sensitivity: 96.7%, Relative Specificity: 100%, Overall agreement: 98.3%

LIMITATIONS

- **This product is an *in vitro* diagnostic test designed for professional use only.**
- **Humidity and temperature can adversely affect results.**
- **The instructions for the use of the test should be followed during testing procedures.**
- **There is always a possibility that false results will occur due to the presence of interfering substances in the specimen or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.**
- **Although the test demonstrates superior accuracy in detecting Typhoid IgG/IgM, a low incidence of false results can occur. Therefore, other clinically available tests are required in case of questionable results. 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.**

REFERENCES

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