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„DIAQUICK“
S. typhi IgG/IgM Ab Cassette

for whole blood, serum and plasma samples

REF

Content

Z11450

- 25 cassettes individually packed (25 x Ref. No: Z11450B)
- 25 10 µL-capillary pipettes
- 1 buffer tube – assay diluent sufficient for 25 tests
- 1 package insert

For In-vitro diagnostic use only

INTENDED USE

The DIAQUICK Salmonella typhi IgG/IgM Ab Cassette is a qualitative in vitro diagnostic immunochromatographic assay for the rapid detection of anti-*S.typhi* antibodies in human whole blood, serum or plasma specimens. The test results are intended to help in the diagnosis of *S. typhi* infection.

SUMMARY

Typhoid fever is a life threatening illness caused by the bacterium *Salmonella typhi*. It was first observed by Eberth in 1880 in the mesenteric nodes and spleen of fatal cases of typhoid fever. The disease is common in developing countries, where it affects about 12.5 million people annually. The infection is typically acquired by ingestion. After reaching the gut, the bacilli attach themselves to the epithelial cells of the intestinal villi and penetrate the lamina and submucosa. There, they are then phagocytosed by polymorphs and macrophages. The ability to resist intracellular killing and to multiply within these cells is a measure of their virulence. They enter the mesenteric lymph nodes, where they multiply and, via the thoracic duct, enter the blood stream. A transient bacteremia follows, during which the bacilli are seeded in the liver, gall bladder, spleen, bone marrow, lymph nodes and kidneys, where further multiplication takes place. Towards the end of the incubation period, there occurs a massive bacteremia from these sites, heralding the onset of the clinical symptoms. The symptoms of the illness include high fever, headache, abdominal pain, diarrhea or constipation. A quick and accurate diagnosis of typhoid fever at an early stage is not only important for etiological diagnosis, but also to identify and treat the potential carriers and prevent acute disease outbreaks.
The DIAQUICK Salmonella typhi IgG/IgM Ab Cassette takes only 10-20 minutes and requires only a small quantity of sample to perform. It is an easy and specific method for detecting *S. typhi* infection.

TEST PRINCIPLE

The DIAQUICK Salmonella typhi IgG/IgM Ab Cassette is a qualitative one step immunochromatographic assay. The test employs *S. typhi* lipopolysaccharide (LPS) to selectively identify anti-*S. typhi* (typhoid) IgG and IgM antibodies with a high degree of sensitivity and specificity.
As the specimen flows through the sample pad, it will react with colloidal gold-anti-human IgG or IgM conjugates. If there are anti-*S. typhi* IgG and/or IgM antibodies present they will form a complex. This complex will continue to move along the nitrocellulose membrane. In the test line region (T), where *S. typhi* specific LPS is immobilized, the complex will be captured by LPS to form a pink/purple band, indicating a positive result.
The absence of the colored test band indicates a negative result.
The remaining complex continues to migrate along the membrane to the control line region (C) and forms a pink/purple band there. The appearance of the control band indicates a proper performance of the test.

MATERIALS PROVIDED

The DIAQUICK Salmonella typhi IgG/IgM Ab Cassette contains following items to perform the assay:

1) 25 test strips individually foil pouched with a desiccant
   Each cassette contains a test strip with *S. typhi* specific LPS on the test region of the membrane and a colored colloidal gold-anti-human IgG and IgM conjugate pad.
2) 25 10 µL-capillary pipettes
3) 1 bottle of assay buffer (5 mL)
4) instructions for use

MATERIALS REQUIRED BUT NOT PROVIDED

1) Specimen collection container
2) Pipette
3) Timer

WARNINGS AND PRECAUTIONS

- This kit is for in vitro diagnostic use only.
- This kit is for professional use only.
- Read the instructions carefully before performing the test.
- This product does not contain any materials of human origin.
- Do not use kit contents after the expiration date.
- Handle all specimens as potentially infectious.
- Follow standard lab procedures and biosafety guidelines for handling and disposal of potentially infectious material. When the assay is completed, dispose of specimens after autoclaving them at 121°C for at least 20 min. Alternatively, they can be treated with 0.5% sodium hypochlorite for 1-2 h before disposal.
- Do not pipette reagents by mouth.
- Do not smoke or eat while performing assays.
- Wear gloves during the whole procedure.

STORAGE INSTRUCTIONS

1) The expiration date is indicated on the package label.
2) The test device can be stored at 2-30°C.

SPECIMEN COLLECTION AND STORAGE

The DIAQUICK Salmonella typhi IgG/IgM Ab Cassette can be run with whole blood, serum or plasma samples.
The test works best with fresh samples. If testing cannot be done immediately, the samples can be stored after collection at 2-8°C for up to 3 days. If testing cannot be done within 3 days, serum can be stored frozen at –20°C or colder.
Shipment of samples should comply with local regulations for transport of etiologic agents.
The specimens should be collected in containers that do not contain media, preservatives, animal serum or detergents, as any of these additives may interfere with the DIAQUICK Salmonella typhi IgG/IgM Ab Cassette.

REAGENT PREPARATION

Bring all reagents, including test device, to room temperature (15-25°C) before use.

TEST PROCEDURE

1) Bring all materials and specimens to room temperature (15-25°C).
2) Remove the test card from the sealed foil pouch.
3) Apply 10 µL of sample to the centre of each sample well (marked as “S”) of both test strips (IgG, IgM), respectively: Depress the middle of the straw pipet to draw whole blood/serum/plasma sample up to the 10 µL volume black mark. Place the straw pipet in the centre of the sample wells and release the sample. Wait about 10 seconds to let the sample be absorbed by the sample pad.
4) Add 2 drops of sample buffer to each sample well.
5) Read the results at 20 minutes. A strong positive sample may show a test band earlier. However, to confirm that a result is negative, read the results not before 20 minutes.

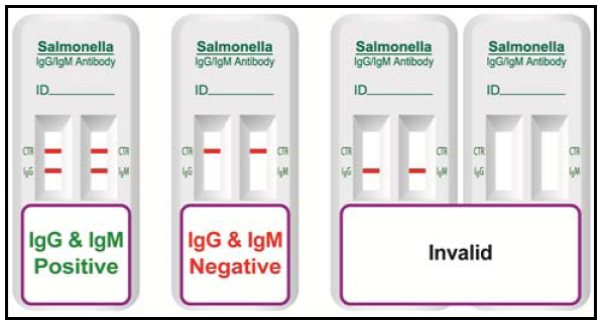
Note: After 30 minutes the results may not be accurate anymore.

INTERPRETATION OF THE TEST

1) Positive result
A distinct pink/purple colored band appears in the test line region, as well as in the control line region.

2) Negative result
No line appears in the test line region. A distinct pink/purple line appears in the control line region.

3) Invalid
The control line does not become visible within 20 minutes after the addition of the sample.



QUALITY CONTROL

1) The control band is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagents are reactive.
2) Good Laboratory Practice recommends the daily use of control materials to validate the reliability of the device. Control materials are not provided with this test kit.

LIMITATIONS

1) The test is for qualitative detection of anti-*S. typhi* IgG and/or IgM antibodies in whole blood, serum or plasma samples and does not indicate the quantity of the antibodies.
2) The test is for in vitro diagnostic use only.
3) For samples, which test positive with the DIAQUICK Salmonella typhi IgG/IgM Ab Cassette, more specific confirmatory testing must be done. A definitive clinical diagnosis should only be made by the physician after all clinical and laboratory findings have been evaluated. The use of a rapid test alone is not sufficient to diagnose a *S. typhi* infection, even if antibodies are present. Also, a negative result does not preclude the possibility of an infection with *S. typhi*.

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