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„DIAQUICK“
S. typhi/paratyphi Ag Cassette

for stool, whole blood, serum and plasma samples

REF

Content

Z11451
- 25 cassettes individually packed (25 x Ref. No: Z11451B)
- 25 buffer tubes
- 1 package insert

For In-vitro diagnostic use only

INTENDED USE

The DIAQUICK Salmonella typhi/paratyphi Ag Cassette is an in vitro diagnostic qualitative immunochromatographic assay for the rapid detection of *S. typhi* and/or *paratyphi* antigens in human stool or whole blood, serum or plasma specimens. The test results are intended to help in the diagnosis of S. *typhi* and/or *paratyphi* infection and to monitor the effectiveness of therapeutic treatment.

SUMMARY

Typhoid and paratyphoid mainly affects poor regions of the world, where sanitation and clean water are lacking. In 2004, the World Health Organization (WHO) estimated that the global annual incidence of typhoid fever to be ~ 19,2 million cases. As the case fatality rate is estimated to be around 4%, this leads to approximately 768,000 deaths per year.

Typhoid is a systemic disease that varies in severity, but nearly all patients experience fever and headache. Some young children will experience a mild illness that is treatable with antibiotics, but they may also suffer from a more severe form of the disease. If the disease is not treated promptly, it can become life threatening. Complications include intestinal haemorrhage and perforation, toxic myocarditis, pneumonia, seizures, typhoid encephalopathy and meningitis. The fatality can be as high as 20% in untreated cases.

Paratyphoid is clinically similar, but the disease is usually milder and of shorter duration. It often manifests as acute gastroenteritis.

The diagnosis of typhoid consists of an isolation of the bacilli and the detection of antibodies. The isolation of the bacilli is very time consuming and antibody detection is not very specific. Other tests include the Widal reaction which lacks both sensitivity and specificity. The DIAQUICK S. typhi/paratyphi Ag Cassette takes only 20 minutes and requires only a small quantity of stool or whole blood, serum or plasma to perform. It is the easiest and most specific method for detecting *S. typhi* and/or *paratyphi* infection.

TEST PRINCIPLE

The DIAQUICK S. typhi/paratyphi Ag Cassette is a qualitative one step immunochromatographic assay. The test employs antibodies specific to lipopolysaccharides (LPS) of *S. typhi* and *S. paratyphi* respectively, to selectively identify typhoid and/or paratyphoid infection with a high degree of sensitivity and specificity.
As the specimen flows through the absorbent pad in the sample well and through the antibody/colloidal gold conjugate, any *S. typhi* antigen and/or *S. paratyphi* antigen present in the sample binds to the conjugate forming an antigen/antibody complex. The complex continues to migrate along the membrane to the test line region, where *S. typhi* and *S. paratyphi* specific LPS antibodies are immobilized on the marked test line regions. In the presence of bacterial antigens, the antibody captures the complex. This forms a visible pink/purple band in the test line region. If no antigen is present, there is no line formation in the test line region. The remaining complexes continue to migrate along the membrane to the control line region (C) and form a pink/purple band. The appearance of the control band indicates a proper performance of the test.

MATERIALS PROVIDED

The DIAQUICK S. typhi/paratyphi Ag 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* and *S. paratyphi* specific antibodies on the test region of the membrane and a colored *S. typhi/paratyphi* antibody-gold conjugate pad.
2) Specimen collection tubes with 1,5 mL dilution buffer each for sample collection and dilution
3) Instructions for use

MATERIALS REQUIRED BUT NOT PROVIDED

1) Specimen collection container
2) 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 4-30°C.

SPECIMEN COLLECTION AND STORAGE

- The DIAQUICK S. typhi/paratyphi Ag Cassette can be run with stool or 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 specimens can be stored frozen at –20°C or colder.
- Stool specimens can be stored at 2-8°C for up to 3 days after suspension in the sample buffer.
- Shipment of samples should comply with local regulations for transport of etiologic agents.
- Stool and whole blood, serum or plasma 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 S. typhi/paratyphi Ag Cassette.
- Repeated freezing and thawing of specimens is not recommended and may cause erroneous results. Do not store specimens in self-defrosting freezers.

REAGENT PREPARATION

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

STOOL SPECIMEN PREPARATION

- Stool specimens can be collected at any time of the day.
- Collect a random sample of feces in a clean, dry receptacle.
- Unscrew the sample bottle, use the attached applicator stick attached on the cap to transfer small piece of stool (4-6 mm in diameter; approx. 200 mg) into the sample bottle containing specimen preparation buffer.
- For liquid or semi-solid stools, add 100 µL of stool to the vial with an appropriate pipette.
- Replace the stick in the bottle and tighten securely. Mix stool sample with the buffer thoroughly by shaking the bottle for a few seconds.

TEST PROCEDURE

1) Remove the test card from the sealed foil pouch. Once opened, the test card must be used immediately.
2) Label the test card with patient’s identity.
3) For stool samples:
   - Thoroughly disperse stool sample and buffer in the collection tube.
   - Hold the sample bottle upright with the tip pointing away from the test performer, snap off the tip.
   - Hold the bottle in a vertical position over the sample well of the test card, deliver 3 drops (120 -150 µL) of diluted stool sample to the sample well.

   For whole blood, serum or plasma samples:
   - Use the provided pipette to transfer the serum sample and add 3 drops to the sample well (marked as “S”).
4) 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: the amount of *S. typhi/paratyphi* antigens present in whole blood, serum or plasma is typically less than that in stool. This may decrease the sensitivity of the test when using whole blood, serum or plasma specimens, depending how soon after the onset of the infection the test is performed. Early infection typically exhibits greater levels of the antigen in the whole blood, serum or plasma than in later infection.

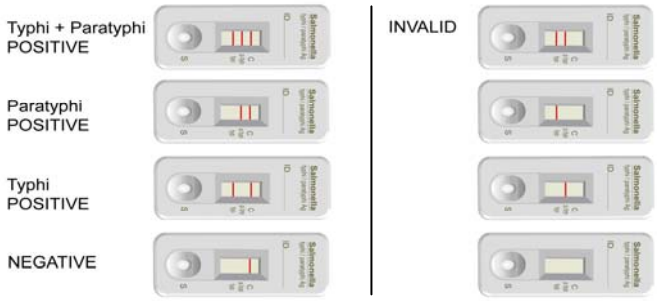
To confirm whole blood, serum or plasma results: the use of a stool sample is recommended if whole blood, serum or plasma is used first and a negative result is obtained and typhoid is still suspected.

INTERPRETATION OF THE TEST

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

2) Negative result
No line appears in the test line regions. 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.

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LIMITATIONS

1) The test is for qualitative detection of *S. typhi* and/or *paratyphi* antigen in stool or whole blood, serum or plasma samples and does not indicate the quantity of the antigens.
2) The test is for in vitro diagnostic use only.
3) For samples, which test positive with the DIAQUICK S. typhi/paratyphi Ag 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/paratyphi* infection, even if antigen is present. Also, a negative result does not preclude the possibility of an infection with *S. typhi/paratyphi*.

PERFORMANCE CHARACTERISTICS

Sensitivity

The analytical sensitivity of *S. typhi* Ag test was determined as 25 ng/mL LPS.
The analytical sensitivity of *S. paratyphi* Ag test was determined as 25 ng/mL LPS.

Specificity

S. typhi Ag test is specific to Salmonella O (somatic) antigen, group D and has no cross with other groups of O antigen tested.
S. paratyphi Ag test is specific to Salmonella O (somatic) antigen, group A and has no cross with other groups of O antigen tested.

Salmonella O antigen	S. typhi	S. paratyphi
A	Negative	**Positive**
B	Negative	Negative
C1	Negative	Negative
C2	Negative	Negative
D	**Positive**	Negative
E2	Negative	Negative
E4	Negative	Negative
G1	Negative	Negative
H	Negative	Negative
I	Negative	Negative
Vi	Negative	Negative

BIBLIOGRAPHY

1) Ivanoff B. Typhoid fever, global situation and WHO recommendations. Southeast Asia J. Trop. Med. Public Health, 1995, 26:supp2 1-6
2) Parry CM, Hien TT Dougan G et al., Typhoid fever, N. Eng. J. Med. 2002, 347:1770-82.

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