

INTENDED USE

Sensit Scrub Typhus Ab Rapid Test is a lateral flow immunoassay for the qualitative detection of antibodies against Scrub Typhus in whole blood, plasma or serum. This test is intended to be used as a screening test and as an aid in the diagnosis of Scrub Typhus infection.

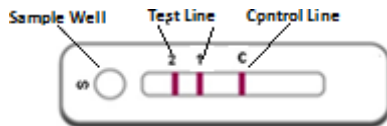
SUMMARY & TEST DESCRIPTION

Typhus is a disease caused by an infection with the Rickettsia bacteria. Fleas, mites (chiggers), lice, or ticks transmit it when they bite you. Fleas, mites, lice, and ticks are types of invertebrate animals known as arthropods. When infected arthropods bite someone, they may leave the bacteria that cause typhus behind. Scratching the bite opens the skin and allows the bacteria to enter the bloodstream. Once in the bloodstream, the bacteria reproduce and grow.

Scrub Typhus antibody Rapid Test is for the qualitative determination of antibodies developed during Scrub Typhus infection.

TEST PRINCIPLE

Sensit Scrub Typhus IgG/IgM Rapid test works on chromatographic immunoassay. Basic components of each test strip includes: a) Conjugate pad which contains colloidal gold conjugate; b) a nitrocellulose membrane strip containing two lines T2: Anti human IgM, T1: Anti human IgG and C: Goat Anti Mouse.



Test specimen, with adequate amount of buffer, migrates along the conjugate pad and further across the coated membrane by capillary action. The sample then continues to migrate across the membrane until it reaches the capture zones where the complex accordingly will bind to the immobilized Anti Human IgG/IgM (on test lines) producing a visible lines on the membrane. If the respective antibody is not present in the sample, no reaction occurs in the capture zones and no test line is formed. If the respective antibody is not present in the sample, no reaction occurs and no test line is formed. The sample then migrates further along the strip until it reaches the control band, where excess Detection-CGC gets bound and produces a second visible line on the membrane. This control line indicates that the sample has migrated across the membrane as intended

REAGENTS & MATERIALS PROVIDED

- Each sealed in a foil pouch containing following items:
 - One test device
 - Desiccant
- Assay Diluent - In dropper bottle
- Instruction Leaflet

PRECAUTIONS & WARNING

- Treat all specimens, used tests and other contaminated materials as infectious, and dispose accordingly.
- Do not use with specimen containing precipitates
- Use within 10 minutes after opening pouch.
- Do not reuse test kit.
- Use only the buffer supplied along with the kit.
- Do not mix components from different kits.
- Use only for in-vitro diagnostic purpose.
- Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.

SAMPLE PREPARATION & STORAGE

- Blood:** Collect the whole blood using a syringe or vacutainer into a container containing anticoagulants such as heparin, EDTA or sodium citrate by venipuncture.
- Plasma:** Collect the whole blood using a syringe or vacutainer (containing anticoagulants such as heparin, EDTA or sodium citrate) by venipuncture. Centrifuge the blood to get plasma specimen as supernatant.
- Serum:** Collect the whole blood using a syringe or vacutainer (NOT containing anticoagulants such as heparin, EDTA or sodium citrate) by venipuncture. Leave the syringe or vacutainer, preferably at an angle, to settle for 30 minutes. Once blood coagulates, centrifuge the blood to get serum specimen as supernatant.
- If the specimen is not used for testing immediately, they should be refrigerated at 2~8°C.
- For storage period longer than 5days, freezing is recommended. Store at -20°C
- The specimen should be brought to room temperature prior to use.

Treat the specimen as infectious and handle with standard biosafety measures.

STORAGE & STABILITY

Store the test kit between 2-30°C till the expiration date indicated on the pouch / carton. DO NOT FREEZE. Ensure that the foil pouch is brought to room temperature before opening.

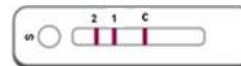
TEST PROCEDURE

- Take out the test card from the foil pouch and place it on a horizontal surface.
- Add 10 µl of Whole Blood/Serum to the Sample well "S"
- When the sample is fully absorbed, add 2 drops of the diluent provided with the assay to the sample hole.
- Wait for 10- 15 minutes and interpret results. The result is considered invalid after 15 minutes. All results where control band does not appear are considered invalid.

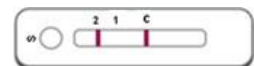


INTERPRETATION OF TEST RESULT

Scrub Typhus IgG&IgM Positive



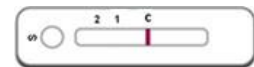
Scrub Typhus IgM Positive



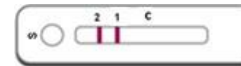
Scrub Typhus IgG Positive



Scrub Typhus Negative



Invalid



Reference:

- P. van Lode (2005). "Point-of-care immunotesting: Approaching the analytical performance of central laboratory methods". Clinical Biochemistry 38
- Advances in detection technologies have enabled new, efficient diagnostics, but only if manufacturers thoroughly understand the assay design process. By: Bonnie J. Stewart, Raymond L. Houghton, WJW Morrow, and Syamal Raychaudhuri