HI-Quik Scrub Typhus IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) Package Insert

A rapid test for the qualitative detection of IgG and IgM antibody to Scrub Typhus in human's whole blood, serum or plasma specimen.
For professional in vitro diagnostic use only.

INTENDED USE: The Scrub Typhus IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibody to Scrub Typhus in human's whole blood, serum or plasma specimen.

SUMMARY : Scrub typhus or bush typhus is a form of typhus caused by the intracellular parasite Orientia tsutsugamushi, a Gram-negative α-proteobacterium of family Rickettsiaceae first isolated and identified in 1930 in Japan.[1,2]
Although the disease is similar in presentation to other forms of typhus, its pathogen is no longer included in genus Rickettsia with the typhus bacteria proper, but in Orientia. The disease is thus frequently classified separately from the other typhi.
Signs and symptoms include fever, headache, muscle pain, cough, and gastrointestinal symptoms. More virulent strains of O. Tsutsugamushi can cause hemorrhaging and intravascular coagulation. Morbilliform rash, eschar, splenomegaly, and lymphadenopathies are typical signs. Leukopenia and abnormal liver function tests are commonly seen in the early phase of the illness. Pneumonitis, encephalitis, and myocarditis occur in the late phase of illness. It has particularly been shown to be the most common cause of acute encephalitis syndrome in Bihar, India.[3]

PRINCIPLE: The Scrub Typhus IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative, lateral flow immunoassay for the detection of IgG and IgM antibody to Scrub Typhus in Whole Blood, serum or plasma. The membrane is pre-coated with anti-human IgG and anti-human IgM on the test line region of the strip. During testing, the whole blood, serum or plasma specimen reacts with the particle coated with Tsutsugamushi recombine antigen. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-human IgG and/or anti-human IgM on the membrane and generate a colored line. The presence of this colored line in the test region(s) indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS : The test cassette contains Tsutsugamushi recombine antigen particles and anti-human IgG and anti-human IgM coated on the membrane.

PRECAUTIONS:
1. The test should remain in the sealed pouch until use.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. The used test should be discarded according to local regulations.
6. Humidity and temperature can adversely affect results.

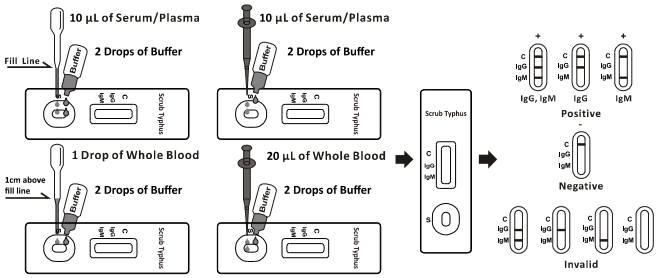
STORAGE AND STABILITY: The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION:
- The Scrub Typhus IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood, serum and plasma specimen.
- Both Fingerstick Whole Blood and Venipuncture Whole Blood can be used.
- To collect **Fingerstick Whole Blood specimens:**
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - Add the Fingerstick Whole Blood specimen to the test by using a **capillary tube:**
    - Touch the end of the capillary tube to the blood until filled to approximately 20µL. Avoid air bubbles.
    - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen well of the test cassette.
- Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 7 days of collection. For long term storage, specimens should be kept below -20°C. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly for more than three times.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.
- EDTA K_2, Heparin sodium, Citrate sodium and Oxalate potassium can be used as anti-coagulants.

MATERIALS:
Materials provided : • Test cassettes • Droppers • Package insert • Buffer
Materials required but not provided : Specimen Collection Containers Centrifuge (For plasma only) * Timer * Lancets (for fingerstick whole blood only)
- * Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

DIRECTIONS FOR USE:
Allow test cassette, specimen, buffer and/or controls to equilibrate to room temperature (15-30℃) prior to testing.
1. Bring the pouch to room temperature before opening. Remove the test cassette from the sealed pouch and use it within one hour.
2. Place the test cassette on a clean and level surface.
   - **For Serum or Plasma Specimens:**
     - To use a dropper: Hold the dropper vertically, **draw the specimen up to the Fill Line** (approximately 10µl), and transfer the specimen to the sample well of the test cassette, then **add 2 drops of buffer** (approximately 80ul) and start the timer. Avoid trapping air bubbles in the specimen well.
     - To use a micropipette: Pipette and dispense **10µl of specimen** to the sample well of the test cassette, then **add 2 drops of buffer** (approximately 80 µl) and start the timer.
   - **For Whole Blood (Venipuncture/Fingerstick) Specimens:**
     - To use a dropper: Hold the dropper vertically, **draw the specimen about 1cm above the Fill Line, and transfer 1 full drop of whole blood** (approximately 20 µl) to the sample well of the test cassette, then **add 2 drops of buffer** (approximately 80 ul) and start the timer.
     - To use a micropipette: **Pipette and dispense 20 µl of whole blood** to the specimen well of the test cassette, then **add 2 drops of buffer** (approximately 80 µl) and start the timer.
3. Wait for the colored line(s) to appear. The test result should be read at **15 minutes**. Do not interpret the result after 20 minutes.

Note: It is suggested not to use the buffer, beyond 6 months after opening the vial.



INTERPRETATION OF RESULTS: (Please refer to the illustration above)

POSITIVE:* Two or three lines appear. One colored line should always appear in the control line region (C) and another one or two apparent colored line(s) should be in the test line region(s) (IgM and/or IgG).

IgM Positive: A colored line appears in control region (C), another colored line appears in IgM region. It indicates a positive test result for IgM antibodies to Scrub Typhus.

IgG Positive: A colored line appears in control region (C), another colored line appears in IgG region. It indicates a positive test result for IgG antibodies to Scrub Typhus.

***NOTE:** The intensity of the color in the test line regions (IgM and IgG) may vary depending on the concentration of Scrub Typhus antibodies present in the specimen. Therefore, any shade of color in the test line region (IgM and/or IgG) should be considered positive.

NEGATIVE: **One colored line appears in the control line region (C)**. No line appears in the test line regions (IgM and IgG).

INVALID: **Control line fails to appear**. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL: Internal procedural controls are included in the test. A red line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS:

1. The Scrub Typhus IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. This test should be used for detection of IgG and IgM antibody to Scrub Typhus in whole blood, serum or plasma specimens. Neither the quantitative value nor the rate of increase in the concentration of Scrub Typhus antibodies can be determined by this qualitative test.
2. The Scrub Typhus IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of Scrub Typhus antibody in the specimen and should not be used as the sole criteria for the diagnosis of Scrub Typhus.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of Scrub Typhus was existed.
5. This Scrub Typhus IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is designed to work with hematocrit level between 25% and 65%. Performance of this test kit at a different hematocrit level can lead to erroneous results.

PERFORMANCE CHARACTERISTICS:

Sensitivity and Specificity:

The Scrub Typhus IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) was compared with the competition Scrub Typhus Rapid; the results indicate that Scrub Typhus IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) has a high sensitivity and specificity.

Performance of IgG Specimen

Method		Other Rapid Test		Total Result
Scrub Typhus IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)	Results	Positive	Negative	
	Positive	46	2	48
	Negative	0	178	178
Total Result		46	180	226

Relative sensitivity: > 99.9% (95%CI*: 93.7%~100%); Relative specificity: 98.9% (95%CI*: 96.0%~99.9%); Accuracy: 99.1% (95%CI*: 96.8%~99.9%).

Performance of IgM Specimen

Method		Other Rapid Test		Total Result
Scrub Typhus IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)	Results	Positive	Negative	
	Positive	28	3	31
	Negative	0	177	177
Total Result		28	180	208

Relative sensitivity: > 99.9% (95%CI*: 89.9%~100%); Relative specificity: 98.3% (95%CI*: 95.2%~99.7%); Accuracy: 98.6% (95%CI*: 95.8%~99.7%). *Confidence Intervals

Precision

Intra-Assay : Within-run precision has been determined by using 3 replicates of these specimens: negative, IgG positive, IgM positive and IgG and IgM Duo positive. The negative, IgG positive, IgM positive and IgG and IgM Duo positive were correctly identified >99% of the time.

Inter-Assay : Between-run precision has been determined by 3 independent assays on the same specimens: negative, IgG positive, IgM positive and IgG and IgM Duo positive. Three different lots of the Scrub Typhus IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) have been tested over a 3-days period using negative, IgG positive, IgM positive and IgG and IgM Duo positive specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity : The Scrub Typhus IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested for HBsAg, anti-HIV, anti-HCV, anti-RF, anti-Spyhilis, anti-H.pylori, anti-Toxo IgG, anti-Rubella IgG, anti-CMV IgG positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following compounds have also been tested using the Scrub Typhus IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) and no interference was observed. :
Acetaminophen: 20 mg/dL Caffeine: 20 mg/dL Acetylsalicylic Acid: 20 mg/dL Gentisic Acid: 20 mg/dL Ascorbic Acid: 2g/dL
Albumin: 2 g/dL Creatin: 200 mg/dL Hemoglobin 1000mg/dL Bilirubin: 1g/dL Oxalic Acid: 60mg/dL

BIBLIOGRAPHY:

1. Tseng BY, Yang HH, Liou JH, Chen LK, Hsu YH (February 2008). "Immunohistochemical study of scrub typhus: a report of two cases". Kaohsiung J. Med. Sci. 24 (2): 92–8.
2. Pediatric Scrub Typhus, access date: 16 October 2011.
3. Jain P, Prakash S, Tripathi PK, et al. (2018). "Emergence of Orientia tsutsugamushi as an important cause of acute encephalitis syndrome in India". PLoS Negl Trop Dis. 12 (3): e0006346.

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