Chlamydia IgM Rapid Test (Whole Blood/Serum/Plasma) For professional use

ELISURE

IVD REF SIC-RDT-CHYA-202050

A rapid test for the qualitative detection of IgM antibody to Chlamydia Trachomatis in human whole blood, serum or plasma.
For professional in vitro diagnostic use only.

INTENDED USE

The Chlamydia IgM Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of IgM antibody to Chlamydia Trachomatis in human whole blood, serum or plasma to aid in the diagnosis of Chlamydia Trachomatis infection.

SUMMARY

Chlamydia Trachomatis are round cells between 0.3 and 1 μm in diameter depending on the stage in the replicative cycle. Their envelope is of the gram-negative type including an outer membrane that contains lipopolysaccharide and proteins. The outer membrane includes a major outer membrane protein (MOMP) which is immunogenic.[1]

Chlamydia trachomatis causes disease in several sites, primarily the conjunctiva and genital tract. In its various forms, this infection is one of the most frequent in the world with an estimated 100 million new cases each year. Humans are the sole reservoir. Inclusion conjunctivitis is seen among population groups in which the strains causing C.trachomatis genital infections are common.[1]

Chlamydial infection is the most frequently reported bacterial infectious disease in the United States, and prevalence is highest among persons aged ⩽24 years. Multiple sequelae can result from C. trachomatis infection among women, the most serious of which include PID, ectopic pregnancy, and infertility. CDC recommends annual screening for all sexually active women < 25 years of age.[2]

PRINCIPLES

The Chlamydia IgM Rapid Test (Whole Blood/Serum/Plasma) is a qualitative, lateral flow immunoassay for the detection of IgM antibody to Chlamydia Trachomatis in whole blood, serum or plasma specimens. In this test, Chlamydia Trachomatis recombinant protein are coated in the test line regions of the test. During testing, the IgM to Chlamydia Trachomatis in whole blood, serum or plasma specimen reacts with mouse anti-human IgM coated particles in the test strip, then the antibody-antigen complex will be captured with Chlamydia Trachomatis recombinant protein in the membrane when migration. The presence of a colored line in the test line region indicates a positive result for Chlamydia infection, while its absence indicates a negative result for that infection.

To serve as a procedural control, a colored line will always appear in the control line region of the strip indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

Materials provided

- Test cassettes
- Package insert
- Buffer
- Droppers

Materials required but not provided

- Specimen collection containers
- Centrifuge
- Pipette
- Lancets (for fingerstick whole blood only)
- Alcohol pad
- Timer

WARNINGS AND PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. Do not smoke, drink, or eat in areas where specimens or kits reagents are handled.
3. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
4. Humidity and temperature may adversely affect results.
5. The used test should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

The Chlamydia IgM Rapid Test can be performed using whole blood, serum or plasma.

1. To Collect **Fingerstick Whole Blood**:
   - Wash the patient's hand with soap and warm water or clean with an alcohol pad. 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.
2. To Collect **Venipuncture Whole Blood**:
   Collect venipuncture whole blood specimen into a collection tube containing EDTA-K2, sodium citrate, heparin sodium and potassium oxalate. Do not use hemolyzed blood for testing. Mix whole blood by inversion and use in the test as outlined in the Test Procedure.
3. To collect **Plasma/Serum**:
   Step 1:
   Collect venipuncture blood specimen into collection tube containing EDTA-K2, sodium citrate, heparin sodium and potassium oxalate for plasma or collection tube without anticoagulants for serum.
   Step 2:
   To prepare plasma specimen, centrifuge collected specimens and carefully transfer the plasma into a new pre-labeled tube.
   To prepare serum specimen, allow blood to clot, centrifuge collected specimens and carefully transfer the serum into a new pre-labeled tube.
4. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens can be stored at 2-8°C for up to 3 days and -20°C for 12 months. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
5. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. It is recommended not to freeze and thaw more than 3 times in both serum and plasma specimens.
6. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

DIRECTIONS FOR USE

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Remove the test from the foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Place the test on a clean and level surface.

For Serum or Plasma specimen:

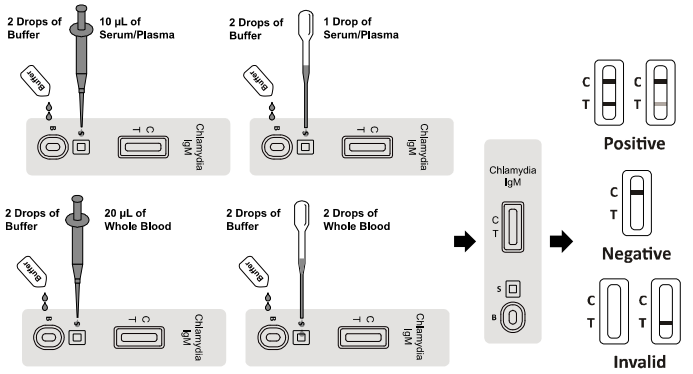
- Use a dropper: Hold the dropper vertically and **transfer 1 full drop of serum or plasma** (approximately **10μL**) to the specimen well(S), then **add 2 drops of buffer** (approximately **80μL**) to the buffer well(B), and start the timer.
- Use a pipette: To **transfer 10μL of serum or plasma** to the specimen well(S), then **add 2 drops of buffer** (approximately **80μL**) to the buffer well(B), and start the timer.

For Whole Blood (Venipuncture/Fingerstick):

- Use a dropper: Hold the dropper vertically, **transfer 2 full drops of whole blood** (approximately **20μL**) to the specimen well(S), then **add 2 drops of buffer** (approximately **80μL**) to the buffer well(B), and start the timer.
- Use a pipette: To **transfer 20μL of whole blood** to the specimen well(S), then **add 2 drops of buffer** (approximately **80μL**) to the buffer well(B), and start the timer.

3. Wait for the colored line(s) to appear. **Read results at 10 minutes**. Do not interpret the result after 20 minutes.

Note: it is suggested not to use the buffer beyond 6 month after opening the vial.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE:* **Two colored lines appear**. One colored line should always appear in the control line region (C) and another colored line should be in the test line region (T).

***NOTE:** The intensity of the color in the test line regions may vary depending on the concentration of Chlamydia Trachomatis IgM present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

NEGATIVE: **One colored line appears in the control line region (C)**. No colored line appears in the test line region (T).

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

A procedural control is included in the test. A colored line appearing in the control line region(C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

LIMITATIONS

1. The Chlamydia IgM Rapid Test (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. This test should be used for detection of IgM antibody to Chlamydia Trachomatis in whole blood, serum or plasma specimens. Neither the quantitative value nor the rate of increase in the concentration of antibodies to Chlamydia Trachomatis can be determined by this qualitative test.
2. The Chlamydia IgM Rapid Test (Whole Blood/Serum/Plasma) will only indicate the presence of antibodies to Chlamydia Trachomatis in the specimen and should not be used as the sole criteria for the diagnosis of Chlamydia Trachomatis infections.
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 Chlamydia Trachomatis infection.
5. The hematocrit of the whole blood should be between 25% and 65%.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The Chlamydia IgM Rapid Test (Whole Blood/Serum/Plasma) was compared with a leading commercial ELISA; the results were tabulated as below.

Method		ELISA		Total Results
Chlamydia IgM Rapid Test	Results	Positive	Negative	
	Positive	32	2	34
	Negative	2	74	76
Total Results		34	76	110

Relative sensitivity: 94.1% (95%CI*: 80.3%~99.3%)
Relative specificity: 97.4% (95%CI*: 90.8%~99.7%)
Accuracy: 96.4% (95%CI*: 91.0%~99.0%) *Confidence Intervals

Limitation of Detection

The minimum detection level is 1:256 forChlamydia IgM positive specimen.

Precision-Repeatability

Precision-repeatability has been determined by using three specimens: negative, weak positive, strong positive specimens. The study was performed 2 replicates per day for 20 consecutive days by one operator using one lot of Chlamydia IgM Rapid Test. No difference was detected in intra lot.

Precision-Reproducibility

Precision-reproducibility has been determined by using three specimens: negative, weak positive, strong positive specimens. The study was performed 5 replicates per

day for 5 consecutive days in 3 different sites using 3 separate lots of Chlamydia IgM Rapid Test (one lot per site), and three operators per site. All results obtained at each site were in agreement with the expected results.

Cross-reactivity

The Chlamydia IgM Rapid Test has been tested for anti-HAV IgG, HBsAg, HBsAb, anti-HCV, anti-HIV, anti-RF, HAMA, anti-Syphilis TP, anti-*H. pylori,* anti-Toxoplasma IgG, anti-Toxoplasma IgM, anti-Rubella IgG, anti-Rubella IgM, anti-CMV IgG, anti-CMV IgM, anti-SARS-CoV-2 positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following compounds have also been tested using the Chlamydia IgM Rapid Test (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: 2 g/dL	Phenylpropanolamine: 20 mg/dL
Bilirubin: 1,000 mg/dL	Phenothiazine: 20 mg/dL
Salicylic Acid: 20 mg/dL	EDTA: 20 mg/dL
Ethanol: 10%	Glucose: 20 mg/dL

BIBLIOGRAPHY

1. KENNETH J. RYAN, Seventh Edition Sherris Medical Microbiology (McGraw-Hill Education, 2018), 709-710.
2. CDC, Chlamydial Infections-Sexually Transmitted Infections Treatment Guidelines, 2021

INDEX OF SYMBOLS

	Consult instructions for use		Contains sufficient for <n> tests
IVD	*In vitro* diagnostic medical device		Use-by date
	Temperature limit	LOT	Batch code
	Do not use if package is damaged		Manufacturer
REF	Catalogue number		Do not re-use

Sicuro Bioengineering Ltd
Address: 19 East West Road,
Port Harcourt - Nigeria
Email: info@sicurobio.com
Website: www.sicurobio.com

Number: M150578502B
Revision date: 2026-07-20