AG- CHIKUNGUNYA IgG/IgM Ab RAPID TEST KIT

INSTRUCTIONS FOR USE

AstraGene Chikungunya IgG/IgM Ab Rapid Test Kit is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to Chikungunya in human's whole blood, serum or plasma. It is intended to be used as a screening test and as an aid in the diagnosis of infection with Chikungunya.

PRINCIPLE

AstraGene Chikungunya IgG/IgM Ab Rapid Test Kit is a qualitative, membrane based immunoassay for the detection of IgG and IgM antibodies to Chikungunya in whole blood, serum or plasma. The membrane is pre-coated mouse anti-human IgG and mouse anti-human IgM on the test line region of the cassette. During testing, the whole blood, serum or plasma specimen reacts with recombinant Chikungunya antigen conjugated colloid gold. The mixture migrates upward on the membrane chromatographically by capillary action to react with mouse anti-human IgG or/and mouse anti-human IgM on the membrane and generate a colored line. Presence of this colored line indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

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PACKAGE CONTENTS

Description	**10 tests**	1 test
Test Cassette and Desiccant	10	1
Dropper	10	1
Buffer	1	1
IFU	1	1

Catalogue Number	**10 tests**	**1 test**
Cassette Model	AG/RTK/CGAb/24/01	AG/RTK/CGAb/24/02

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Clock or timer.
- Specimen collection containers
- Centrifuge
- Lancets (for fingerstick whole blood only)
- Pipette
- Latex gloves

STORAGE &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 & PREPARATION

- AstraGene Chikungunya IgG/IgM Ab Rapid Test can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.

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 40 uL. 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 area of the test cassette.
- Add the Fingerstick Whole Blood specimen to the test by using hanging drops:
- Position the patient's finger so that the drop of blood is just above the specimen area of the test cassette.
- Allow 1 hanging drop of fingerstick whole blood to fall into the center of the specimen area on the test cassette, or move the patient's finger so that the hanging drop touches the center of the specimen area. Avoid touching the finger directly to the specimen area.
- 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 the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. 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.
- 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.
- If specimens are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.

PROCEDURE

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

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the cassette on a clean and level surface.

For Serum or Plasma specimen:

- Hold the dropper vertically and **transfer 1 drop of serum or plasma** (approximately 40 uL) to the specimen area, then **add 2 drops of buffer** (approximately 80 uL),and start the timer, see illustration below.

For Venipuncture Whole Blood specimen:

- Hold the dropper vertically and **transfer 1 drop of whole blood** (approximately 40 uL) to the specimen area, then **add 2 drops of buffer** (approximately 80 uL), and start the timer. See illustration below.

For Fingerstick Whole Blood specimen:

- To use a capillary tube: Fill the capillary tube **and transfer approximately 40 uL of fingerstick whole blood specimen** to the specimen area of test

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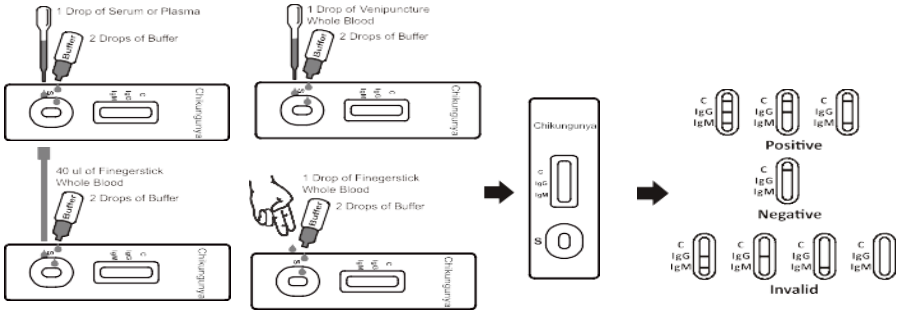
cassette, then **add 2 drops of buffer** (approximately 80 uL) and start the timer. See illustration below.

- To use hanging drops: Allow **1 hanging drop of fingerstick whole blood specimen** (approximately 40 uL) to fall into the specimen area of test cassette, then **add 2 drops of buffer** (approximately 80 uL) and start the timer. See illustration below.

3. Wait for the colored line(s) to appear. **Read the result at 15 minutes,** do not interpret the result after 20 minutes.



RESULT INTERPRETATIONS

IgG POSITIVE: Two colored lines appear. One colored line should be in the control region (C) and another colored line should be in the IgG region.
IgM POSITIVE: Two colored lines appear. One colored line should be in the control region (C) and another colored line should be in the IgM region.
IgG and IgM POSITIVE: Three colored lines appear. One colored line should be in the control region (C) and another two colored lines should be in the IgG and IgM region.
NOTE: The intensity of the colored in the test line region (T) will vary depending on the concentration of Chikungunya antibodies present in the specimen. Therefore, any shade of red in the test region should be considered positive.
NEGATIVE: One colored line appears in the control region (C). No line appears in the IgG and IgM region.
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 kit. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

SPECIFICITY AND SENSITIVITY

Performance of AstraGene Chikungunya IgG/IgM Ab Rapid Test in comparison with a commercial Chikungunya IgM EIA kit was as observed below:
IgM Results: Relative sensitivity: 90.3% (95%CI:*81.0%-96.0%) ; Relative specificity: ＞99.9% (95%CI:*86.7%-100%) ; Accuracy: 92.5% (95% CI: *85.1% - 96.9%) *Confidence Intervals
IgG Results: Relative sensitivity: 94.3% (95%CI:*80.8%-99.3%); Relative specificity: 97.0% (95%CI:*84.2%-99.9%); Accuracy: 95.6% (95%CI:*87.6%-99.1%) *Confidence Intervals

LIMITATION OF THE PROCEDURE

- The Direction for Use and the Interpretation of Result must be closely when testing the presence of antibodies to Chikungunya in serum, plasma or whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.
- The AstraGene Chikungunya IgG/IgM Ab Rapid Test Kit is limited to the qualitative detection of antibodies to Chikungunya in human serum, plasma or whole blood. The intensity of the test band does not have linear correlation with antibody titer in the specimen.
- A negative result for an individual subject indicates absence of detectable Chikungunya antibodies. However, a negative test result does not preclude the possibility of exposure to Chikungunya.
- A negative result can occur if the quantity of Chikungunya antibodies present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
- The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

WARNING AND PRECAUTION

- For professional in vitro diagnostic use only. Do not use after expiration date.
- The test should remain in the sealed pouch until use.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- 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.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

SYMBOLS

Do not use if package is damaged Manufacturer LOT Batch Code

CE mark of Conformity Refer to the instructions ISO 13485:2016 ISO GMP

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