AG-DENGUE Ag+Ab RAPID TEST KIT

INTENDED USE

AstraGene's Dengue Ag + Ab Rapid Test Kit is a lateral flow chromatographic immunoassay for the qualitative detection of Dengue virus IgG/IgM antibody and NS1antigen in human serum ,plasma or whole blood. It is intended to be used as a screening test and as an aid in the diagnosis of infection with Dengue viruses. Any reactive specimen with the Dengue IgG/IgM+NS1 antigen Rapid Test must be confirmed with alternative testing method(s) and clinical findings.

PRINCIPLE

The AstraGene's Dengue Ag + Ab Rapid Test Kit is a lateral flow chromatographic immunoassay. The test cassette consists of IgG/IgM Strip and NS1 strip. IgG/IgM strip:1) a colored conjugate pad containing Dengue recombinant envelope antigens conjugated with colloid gold (Dengue conjugates) and rabbit IgG-gold conjugates,2) a nitrocellulose membrane strip containing two test bands (G and M bands) and a control band (C band). The G band is pre-coated with the antibody for the detection of IgG anti-Dengue virus, M band is coated with antibody for the detection of IgM anti-Dengue virus, and the C band is pre-coated with goat anti rabbit IgG.

NS1 strip:1) a colored conjugate pad containing mouse anti-Dengue NS1 antigen conjugated with colloid gold (Dengue Ab conjugates), 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with rabbit anti-Dengue NS1 antigen, and the C band is pre-coated with goat anti-mouse IgG antibody.

IgG/IgM strip: When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. IgG anti-Dengue virus if present in the specimen will bind to the Dengue conjugates. The immunocomplex is then captured by the reagent coated on the G band, forming a colored G band, indicating a Dengue virus IgG positive test result and suggesting a recent or repeat infection. IgM anti-Dengue virus, if present in the specimen, will bind to the Dengue conjugates. The immunocomplex is then captured by the reagent pre-coated on the M band, forming a colored M band, indicating a Dengue virus IgM positive test result and suggesting a fresh infection. Absence of any test bands (G and M) suggests a negative result.The test contains an internal control (C band) which should exhibit a colored band of the immunocomplex of goat anti rabbit IgG/rabbit IgG-gold conjugate regardless of the color development on any of the T bands. Otherwise, the test result is invalid and the specimen must be retested with another device.

NS1 Strip: When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the test cassette. Dengue NS1 Ag if present in the specimen will bind to the Dengue Ab conjugates. The immunocomplex is then captured on the membrane by the pre-coated rabbit anti-NS1 antibody, forming a colored T band, indicating a Dengue Ag positive test result. Absence of the T band suggests a negative result. The test contains an internal control (C band) which should exhibit a colored band of the immunocomplex of goat anti-mouse IgG/mouse IgG-gold conjugate regardless of the presence of colored T band. Otherwise, the test result is invalid and the specimen must be retested with another device.

PACKAGE CONTENTS

Description	10 tests	1 test
Test Cassette and Desiccant	10 Cassette	Cassette
Sample dropper	10 Nos	1 No.
Reagent Solution Bottle	1 No	1 No
Instruction for use	1 Nos	1 No.

Catalogue Number	10 tests	1 test
Cassette Model	AG/RTK/DVAgAb/21/01	AG/RTK/DVAgAb/21/02

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Clock or timer.
- Pipette
- Latex gloves

STORAGE &STABILITY

- Test device in the sealed pouch should be stored at 2-30ºC. Do not freeze the test device.
- The bottle containing the buffer should be stored at 2-30ºC.
- The test device should be kept away from direct sunlight, moisture and heat.

SPECIMEN COLLECTION & PREPARATION

Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

- **Plasma**
  1.Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by veinpuncture.
  2.Separate the plasma by centrifugation.
  3.Carefully withdraw the plasma into new pre-labeled tube.
- **Serum**
  1.Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by veinpuncture.
  2.Allow the blood to clot.
  3.Separate the serum by centrifugation.
  4.Carefully withdraw the serum into a new pre-labeled tube.
  5.Test specimens as soon as possible after collecting. Store specimens at 2°C to 8°C if not tested immediately.
  6.Store specimens at 2°C to 8°C up to 5 days. The specimens should be frozen at -20°C for longer storage
- **Blood**
  1. Drops of whole blood can be obtained by either finger tip puncture or veinpuncture. Do not use any hemolized blood for testing.
  2. Whole blood specimens should be stored in refrigeration (2°C-8°C) if not tested immediately. The specimens must be tested within 24 hours of collection.Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

PROCEDURE

A) Remove the testing device from the sealed pouch by tearing at the notch and place the testing device on a leveled surface.	

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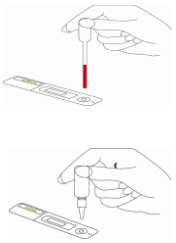
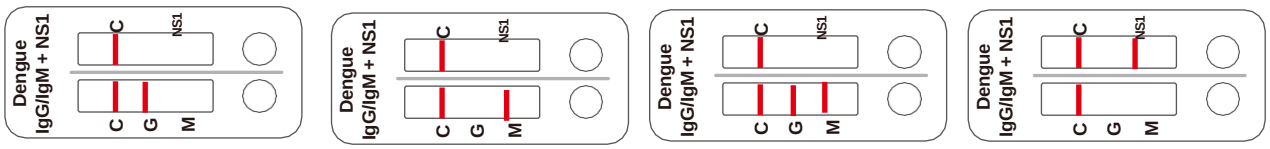
B) For Both Whole Blood Sample and Serum/plasma Sample: • Hold the sample dropper vertically. Add 1 drop (35-40 µl) of the specimen without air bubbles into the Sample Well that is marked with an arrow on the testing device; • Wait for 20-30 sec. Add 2 drops (90-100 µl) of the assay buffer to the same Sample Well of the testing device.	
c) Read the result in 10-30 minutes. Read results as shown under interpretation of Results NOTE: Strong positive specimens may produce positive result in as little as 1 minute. Confirm negatives in 10-20 minutes (for whole blood samples, confirm negatives in 20-30 minutes). DO NOT INTERPRET RESULTS AFTER 40 MINUTES.	

RESULT INTERPRETATION

Positive

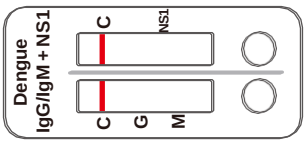
A clear pink control band (C) and a detectable test band (T) appear, indicating a positive result.

IgG Positive | IgM Positive | IgG & IgM Positive | NS1 Ag Positive



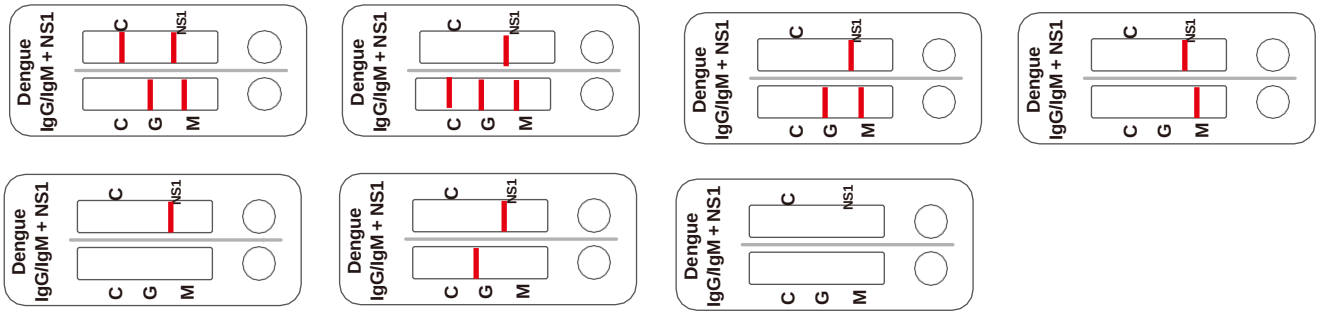
Negative:

A pink colored band appears only at the control region (C), indicating a negative result



Invalid

No visible band appears at the control region. Repeat with a new test kit. If the test still fails, please contact the distributor with the lot number



PERFORMANCE CHARACTERISTICS

Clinical Performance For IgM Test compared by a commercial EIA: Relative Sensitivity:96.15% , Relative Specificity:99.41%, Overall Agreement: 98.66%

Clinical Performance For IgG Test compared by a commercial EIA: Relative Sensitivity: 96.0% , Relative Specificity: 99.56%, Overall Agreement: 98.91%

Clinical Performance For NS1 Test compared by a commercial EIA: Relative Sensitivity: 97.5% , Relative Specificity: 99.67%, Overall Agreement: 99.21%

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LIMITATION OF THE PROCEDURE

- The Assay Procedure and the Test Result Interpretation must be followed closely when testing the presence of antibodies and NS1 antigens to Dengue virus in serum, plasma or whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.
- AstraGene's Dengue Ag + Ab Rapid Test Kit is limited to the qualitative detection of antibodies and NS1 antigen to Dengue virus in human serum, plasma or whole blood. The intensity of the test band does not have linear correlation with the antibody titer in the specimen.
- AstraGene's Dengue Ag + Ab Rapid Test Kit cannot be used to differentiate if the infection is primary or secondary.
- Serological cross reactivity with other flaviviruses is common (e.g., Japanese encephalitis, West Nile, yellow fever, etc.), therefore, it is possible that patients infected with these viruses may show some level of the reactivity with this test.
- A negative or non-reactive result for an individual subject indicates absence of detectable Dengue virus antibodies and NS1 antigen. However, a negative or non- reactive test result does not preclude the possibility of exposure to or infection with Dengue virus.
- A negative or non-reactive result can occur if the quantity of the dengue virus 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. Therefore, a follow up test or alternative tests such antigen test or PCR test method is recommended if the clinical findings strongly suggest an infection or when there is an outbreak.
- If the symptom persists, while the result from AstraGene's Dengue Ag + Ab Rapid Test Kit is negative or non-reactive result, it is recommended to re-sample the patient few days late or test with an alternative test device.
- Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
- 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.
- This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
- Do not open the sealed pouch, unless ready to conduct the assay.
- Do not use expired devices.
- Bring all reagents to room temperature (15°C-30°C) before use.
- Do not use the components in any other type of test kit as a substitute for the components in this kit.
- Do not use hemolized blood specimen for testing.
- Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
- Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
- Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
- Dispose of all specimens and materials used to perform the test as biohazardous waste.
- Handle the Negative and Positive Control in the same manner as patient specimens.
- The testing results should be read within 25 minutes after a specimen is applied to the sample well or sample pad of the device. Read result after 25 minutes may give erroneous results.
- Do not perform the test in a room with strong air flow, ie. electric fan or strong air-conditioning.

 Do not use if package is damaged  Manufacturer  Batch Code

 CE mark of Conformity  Refer to the instructions  ISO  GMP

AstraGene FZ LLC, Office No. 208 – 209, Dubai Science Park Building, Dubai, United Arab Emirates
+971-4-8781222, contact@astragene.com