

INTENDED USE

The kit is IVD rapid test for qualitative detection of HSV 1/11gG/IgM antibodies in human whole blood, serum or plasma specimen.

PRINCIPLE

The HSV 1/11 IgG/IgM Antibody Rapid Test Cassette (Colloidal Gold) is a qualitative membrane strip based immunoassay for the detection of HSV 1/11 antibodies (IgG and IgM) in Serum/Plasma and whole blood. The test device consists of: 1) a burgundy colored conjugate pad containing HSV 1/11 recombinant envelope antigens conjugated with Colloid gold (HSV conjugates), 2) a nitrocellulose membrane strip containing two test bands (T1 and T2 bands) and a control band (C band). The T1 band is pre-coated with Mouse anti-human IgM monoclonal antibody for the detection of HSV 1/11 IgM Antibody, T2 band is coated with Mouse anti-human IgG monoclonal antibody for the detection of HSV 1/11 IgG Antibody, and the C band is pre-coated with Mouse anti-HSV antibody. 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. IgM anti-HSV 1/11, if present in the specimen, will bind to the HSV 1/11 recombinant envelope antigens conjugates. The immunocomplex is then captured by the reagent pre-coated on the T1 band, forming a burgundy colored T1 band indicating a HSV 1/11 IgM positive test result and suggesting a recent or repeat infection. IgG anti-HSV 1/11 if present in the specimen will bind to the HSV 1/11 recombinant antigens conjugates. The immunocomplex is then captured by the reagent coated on the T2 band, forming a burgundy colored T2 band, indicating a HSV 1/11 IgG positive test result and suggesting a Previous infection. Absence of any T bands (T1 and T2) suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of Mouse anti-HSV antibody/ HSV 1/11 recombinant antigens 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.

COMPONENTS

MATERIALS PROVIDED

- HSV 1/11 IgG/IgM Antibody Rapid Test Cassette (Colloidal Gold)
- Assay buffer
- Lancet
- Alcohol Wipe
- Pipette
- Package Insert

MATERIALS NOT PROVIDED BUT REQUIRED

- Timer

PRECAUTIONS

- For professional in vitro diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged.
- Do not reuse tests.
- Avoid cross-contamination of specimen by using a new specimen container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not interchange or mix reagents from different lots.
- Humidity and temperature can adversely affect results.
- Used Testing materials should be discarded according to local regulations.

STORAGE AND STABILITY

- The kit should be stored at 2-30° (until the expiry date printed on the sealed pouch).
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Cares should be taken to protect components in this kit from contamination.
- Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments, containers can lead to false.

SPECIMENS COLLECTION

Whole Blood

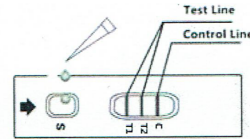
- Whole blood can be used for test immediately.

Serum and Plasma

- Plasma sample can be treated with heparin, sodium citrate, and EDTA. Serum or plasma sample can be stored at 2-8 °C for 8 days, at least 3 months below -18 °C.
- Do not repeated freezing and thawing. If there's turbidity and sediment in sample, centrifuge it first. Take the clear liquid for testing.

ASSAY PROCEDURE

1. Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well prior to assay once thawed.
2. When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.
3. Be sure to label the device with specimen's ID number.
4. Add 1 drop (30 µL) whole blood/ serum/ plasma into the sample well, making sure that there are no air bubbles. Then add 2 drop (about 60-70 µL) of assay buffer immediately.
5. Set up timer.
6. Results can be read in 20 minutes. Don't read result after 20 minutes. To avoid confusion, discard the test device after interpreting the result.



INTERPRETATION OF RESULTS

NEGATIVE RESULT:

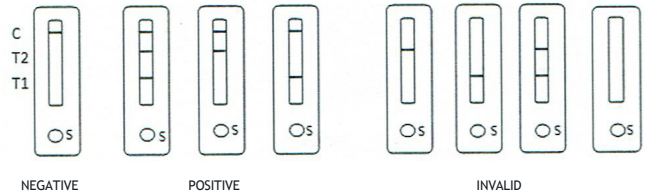
- If only the C band is present, the absence of any burgundy color in the both T bands (T1 and T2) indicates that no HSV 1/11 IgG/IgM antibodies are detected in the specimen.

POSITIVE RESULT:

- In addition to the presence of C band, if only T1 band is developed, the test indicates for the presence of HSV 1/11 IgM antibody. The result is positive.
- In addition to the presence of C band, if only T2 band is developed, the test indicates for the presence of HSV 1/11 IgG. The result is positive.
- In addition to the presence of C band, both T1 and T2 bands are developed, the test indicates for the presence of HSV 1/11 IgG and IgM. The result is also positive.
- Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.

INVALID:

- If no C band is developed, the assay is invalid regardless of any burgundy color in the test bands as indicated below. Repeat the assay with a new device.



LIMITATION

1. The Assay Procedure and the Test Result Interpretation must be followed closely when testing the presence of antibodies to Herpes simplex virus IgG/IgM Antibody in serum, plasma or whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The HSV 1/11 IgG/IgM Antibody Rapid Test Cassette (Colloidal Gold) is limited to the qualitative detection of antibodies to HSV 1/11 antibody 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.
3. A negative result for an individual subject indicates absence of detectable HSV 1/11 antibodies. However, a negative test result does not preclude the possibility of exposure to HSV 1/11 antibody.