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# HIV 1/2/0 Antibody Rapid Test (Colloidal Gold)

[ For qualitative detection of IgG anti-HIV-1, anti-HIV-2 and anti-HIV-O antibodies in human serum/ plasma or whole blood]

## INTENDED USE

The HIV 1/2/0 Antibody Rapid Test is an indirect lateral flow chromatographic immunoassay for the simultaneous detection and differentiation of IgG anti-HIV-1 ,anti-HIV-2 and anti-HIV-O antibodies 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 HIV. Any reactive specimen with the HIV -1/2/0 Antibody Rapid Test must be confirmed with alternative testing methods

## PRINCIPLE

The HIV 1/2/0 Antibody Rapid Test is an indirect lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing mouse monoclonal anti-human IgG antibody conjugated with colloid gold (Human IgG 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 recombinant HIV-1 antigen gp 120 / gp41 and HIV-2 antigen gp36 for the detection of antibodies to HIV-1 and HIV-2, T2 band is pre-coated with HIV-O antigen gp120/gp41 for the detection of antibodies to HIV-O, and the C band is pre-coated with goat anti-mouse IgG 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. IgG anti-HIV-1 antibodies or IgG anti-HIV-2 antibodies if present in the sample migrate through the conjugate pad where they bind to the Human IgG conjugates. The immunocomplex is then captured on the membrane by the pre-coated HIV-1 or HIV-2 antigen, forming a burgundy colored band on the T1 region, indicating a positive test result. Absence of this band in the test region suggests a HIV -1 and/or HIV-2 antibody negative result.

IgG anti -HIV-O antibodies if present in the sample migrate through the conjugate pad where they bind to the Human IgG Conjugates. The immunocomplex is then captured on the membrane by the pre-coated HIV-O antigen, forming a burgundy colored band on the T2 region, indicating a positive test result. Absence of this band in the test region suggests a HIV -0 antibody negative result.

The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti mouse IgG/ mouse anti-human IgG conjugates regardless of the presence of any colored T bands. Otherwise, the test result is invalid and the specimen must be retested with another device.

## COMPONENTS

## MATERIALS PROVIDED

- HIV 1/2/0 Antibody Rapid Test (Colloidal Gold)
- Pipette
  Buffer
- Lancet
- Alcohol Wipe
- 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.
- All patient samples should be treated as if capable of transmit-ting diseases.
- Used Testing materials should be discarded according to local regulations.

## STORAGE AND STABILTY

- The kit should be stored at 2-30 °C 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 or reagents can lead to false results.

## SPECIMENS COLLECTION

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

**Plasma**

- Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate orheparin,respectively in Vacutainer by vein puncture.
- Separate the plasma by centrifugation.
- Carefully withdraw the plasma into new pre-labeled tube.

**Serum**

- Collect blood specimen into a red top collection tube containing no anticoagulants in Vacutainer by veinpuncture.
- Allow the blood to clot.
- Separate the serum by centrifugation.
- Carefully withdraw serum into a new pre-labeled tube. Test specimens as soon as possible after collecting. Store specimens at 2C-8C if not tested immediately. Store specimens at 2C - 8C up to 5 days. The specimens should be frozen at -20C for longer storage.
- Avoid multiple freeze-taw 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. Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

**Whole blood**

- Drops of whole blood can be obtained by either finger tip puncture or vein puncture. Do not use any hemolized blood for testing.
- Whole blood specimens should be stored in refrigeration if not tested immediately. The specimens must be tested within 24hours of collection.

## ASSAY PROCEDURE

- Bring the specimens and test components to room temperature if refrigerated or frozen. Mix the specimen well prior to assay once thawed.
- When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.
- Be sure to label the device with specimen's ID Number.

**For Whole Blood Test**

- Dispense 1 drop (about 30µL) of the specimen into sample well,
- Then add 2 drops (about 60µL) of buffer immediately

**For serum or plasma test**

- Dispense 1 drop (about 30µL) of the specimen into the sample well,
- Then add 2 drops (about 760-70 µL) of buffer immediately
- Set up timer.
- Results can be read in 20 minutes. Positive results can be visible in as short as 1 minute.
- Don't read result after 20 minutes. To avoid confusion, discard the test device after interpreting the result.

20 L of serum/plasma 2 drops of buffer

1 drop of blood 1 drop of buffer

## 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 HIV antibodies are detected in the specimen.

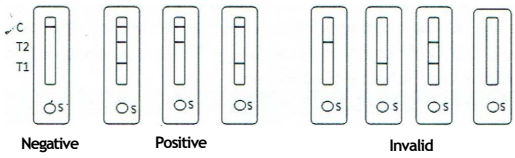
**POSITIVE RESULT:**

- In addition to the presence of C band, if T1 band is developed, the test indicates for the presence of antibodies to HIV-1 or HIV-2 in the specimen. The result is HIV-1/HIV-2 positive.
- In addition to the presence of C band, if T2 band is developed ,the test indicates for the presence of antibodies to HIV-O in the specimen. The result is HIV-O positive.
- In addition to the presence of C band, if both T1 and T2 bands are developed, the test indicates for the present antibodies to HIV 1/2 and HIV 0. The rest result is HIV positive. To differentiate the type of virus infection, dilute the specimen at 1:100 dilution with the buffer provided, re-run the test. Interpret the result as illustrated above (also See Limitations of Test 5.).

**Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.**

**INVALID RESULT:**

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




## LIMITATIONS

1. The Assay Procedure and the Test Result Interpretation must be followed closely when testing the presence of antibodies to HIV in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The HIV 1/2/0 Antibody Rapid Test is limited to the qualitative detection of antibodies to HIV-1/2 or HIV-O 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 HIV-1/2 or HIV-O antibodies. However, a negative test result does not preclude the possibility of exposure to or infection with HIV-1 /2 or HIV-O.
4. A negative result can occur if the quantity of the HIV-1 /2 or HIV-O 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.
5. As illustrated in INTERPRETATION OF ASSAY RESUL T-2.3, all the three positive bands (T1, T2 and C) may develop when tested with samples containing high titer of HIV-1/2 antibodies. To differentiate the cross reactivity: dilute the test specimen with buffer at 1: 100 dilution, then re-test the diluted specimen with a new test device. Only T1 band and C will appear if it is a HIV-1/2Ab response. If T1, T2 and C band all appear, the test indicates for the exposure of both HIV-1 /2 and HIV-O.
6. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
7. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

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