Diagnostic Automation / Cortez Diagnostics, Inc.
IMMUNO DIAGNOSTICS

OneStep HIV 1+2 RapiCard™ InstaTest Serum, WB, Plasma

Cat #177575-1-12

"Export Use Only"

IVD See external Label 2°C 30°C Σ 40 Tests

Sensitvity	99%
Specificity	100%
Generation	3rd Generation

INTENDED USE

This test is a single use, rapid device for qualitative detection of antibodies to Human Immunodeficiency Viruses (HIV) in whole blood, serum and plasma samples."Export Use Only"

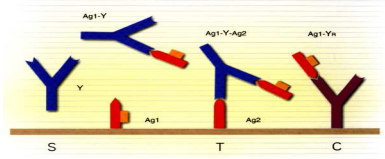
SUMMARY AND EXPLANATION

The Human Immunodeficiency Viruses type 1 and type 2 are etiological agents of the acquired immunodeficiency syndrome (AIDS). HIV has been isolated from patients with AIDS, AIDS related complex (ARC) and from healthy individuals at high risk for (AIDS). Infection with HIV is followed by an acute flu-like illness. This phase may remain unnoticed and the relationship to HIV infection may not be clear in many cases. The acute phase is typically followed by an asymptomatic carrier, which progresses to clinical AIDS in about 50% of infected individuals within 10 years after seroconversion.

Serological evidence of HIV infection may be obtained by testing for HIV antigens or antibodies. Antigen to HIV can be detected throughout virtually the total infection period, starting at or shortly after the acute phase and lasting until the end stage of AIDS. Therefore, the use of highly sensitive antibody assays is the primary approach in serodiagnosis of HIV infection.

TEST PRINCIPLE

This test employs chromatographic lateral flow device in a cassette format. Colloidal gold conjugated recombinant antigens (Au-Ag) corresponding to HIV-1 gp120, gp41 and HIV-2 gp-36 are dry-immobilized at the end of nitrocellulose membrane strip. HIV 1+2 antigens are bond at the Test Zone (T) and rabbit anti-HIV 1+2 monoclonal antibodies are bond at the Control Zone (C). When the sample is added, it migrates by capillary diffusion rehydrating the gold conjugate. If present in sample, HIV 1/2 antibodies will bind with the gold conjugated antigens forming particles. These particles will continue to migrate along the strip until the Test Zone (T) zone where they are captured by the HIV 1+2 antigens generating a visible red line. If there are no HIV 1 or 2 antibodies in sample, no red line is formed in the Test Zone (T).The gold conjugate will continue to migrate alone until it is captured in the Control Zone(C) by the rabbit anti-HIV 1+2 antibodies aggregating in a red line, which indicates the validity of the test.



Y	HIV 1/2 Antibodies in sample.
Ag1	Au-Ag in S (Sample Pad Window).
Ag1-Y	Au-Ag-HIV 1/2 Antibody Complex.
Ag2	HIV 1/2 Antigens immobilized in the Test Zone (T).
Ag1-Y-Ag2	Double Antigen Sandwich Complex in the Test Zone (T).
Ag1-Y_R	Au-Ag-Rabbit anti-HIV complex in the Control zone (C).

SPECIMEN COLLECTION AND PREPARATION

Whole blood:
Wash your hands with soap and warm water. Choose a puncture site on the fingertip. Clean the fingertip with Alcohol Prep Pad. Place a Safety Lancet on a selected puncture site. Forcefully press the tip of the Safety Lance against your fingertip. Wipe away the first drop of blood with sterile gauze or cotton Using Disposable Pipette, collect blood from the puncture site. Alternatively - draw blood following laboratory procedure for obtaining venous blood. Do not test whole blood samples if older than 3days.

Serum/plasma samples:
Fresh serum or plasma samples can be used. No special patient preparation required. Care should be taken to ensure blood full clotting and any visible particulate matter in the sample should be removed by centrifugation or filtration. Avoid the use of highly hemolytic, turbid, microorganism contaminated samples or samples stored for over 30days at 2-8 °C. Store samples at 2-8 °C. Samples not required for assay within 3 days should be stored frozen (-20 °C or lower). Avoid sample deterioration by multiple freeze-thaw cycles.

Plasma: Collect whole blood into a collection tube (containing EDTA, citrate or heparin, respectively) by venipuncture. Separate the plasma by centrifugation.

Serum: Collect whole blood into a collection tube (containing no anticoagulants) by venipuncture. Allow the blood to clot. Separate by centrifugation

MATERIALS AND COMPONENTS

Materials provided with the test kits

1. HIV (1+2) colloidal gold rapid test in white plastic cassette packed in foil pouch.
2. Instructions for use.
3. Diluent buffer.
4. The dilution buffer can be stored at room temperature. Stable for one month after opening.

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Materials required but not provided

1. Clock or timer.
2. Specimen collection container.
3. Centrifuge.
4. Biohazard waste container.
5. Sterile gauze or cotton.
6. Single use only whole blood samples collection pipettes and safety lancet.

ASSAY PROCEDURE

Procedure for whole blood samples: Open the pouch and pipette 50µl of blood into the sample window (S). Add 50µl (or about one drop) of Diluent Buffer into the sample window. **Procedure for serum/plasma samples:** Open the pouch and add 80µl of serum or plasma into the sample window (S). Avoid dropping sample or buffer in the observation window. Do not allow the sample to overflow. Place the cassette on flat surface and read the results within 10 to 30 minutes. A positive test line may appear after 30minutes-this is a False Positive Result-do not read the results after 30 minutes.

RESULTS

- **Quality Control:** One red line will always appear next to the Control Zone(C) indicating the validity of the test. If no red line appears, the test is invalid - discard the test and repeat with new sample and new cassette.
- **Positive Results:** One red line next to the Test Zone (T) indicates that antibodies to HIV 1+2 have been detected using this HIV 1+2 Rapid Test.
- **Negative Results:** No red line appears within 30 minutes next to the Test Zone (T) indicating that no antibodies to HIV 1+2 have been detected with this HIV 1+2 Rapid Test. However, this does not exclude the possibility from infection with HIV.

POSITIVE NEGATIVE INVALID

When the result of the test is positive, please contact your doctor. The positive result obtained with this Diagnostic Automation, Inc. HIV 1+2 Rapid Test alone cannot be the final diagnosis of HIV. Any positive result must be interpreted in conjunction with the patient clinical history and another laboratory testing results. Follow-up and supplementary testing of all positive samples with other analytical system (e.g.ELISA, WB) is required to confirm any positive result.

PERFORMANCE CHARACTERISTICS

In a clinical evaluation of the performance of Diagnostic Automation, Inc. HIV 1/2 Rapid Test using 2657 confirmed negative and 667 positive samples, sensitivity was 99.4% (666/667) and specificity was 100% (2657/2657). The overall agreement with the reference ELISA tests is 100%. Accuracy of 99% based on internal Quality Control standards.

Sites	HIV pos.sera		HIV neg.sera	
	Total	Positive	Total	Neative
(1)	50	49	200	200
(2)	119	119	61 anti-HCV (+) 113 HBsAg (+) 110 TP (+) 1500 n. sera	61 113 110 1500
(3)	149	147	173	173
(4)	102	102	198	198
(5)	200	200	100anti-HCV (+) 2 RF (+)	100 2
(6)	50	49	10 Anti-HAV (+) 50 HBsAg (+) 40 TP (+) 100 N. sera	10 50 40 100
Total	**670**	**666**	**2657**	Error! No book mark name given

LIMITATIONS OF PROCEDURE

1. Negative results do not exclude the possibility of HIV exposure or infection. Infection through recent exposure (seroconversion) to HIV may not be detectable. For positive results, line intensity cannot be used to evaluate the anti-HIV antibody levels. A test giving an invalid result should be repeated. This HIV (1+2) Rapid Test does not differentiate between recognition of HIV-1 antibodies and HIV-2 antibodies.
2. If, after retesting of the initially reactive samples, the test results are negative, these samples should be considered as non-repeatable (false positive) and interpreted as negative. As with many very sensitive rapid diagnostic tests, false positive results can occur due to the several reasons, most of which are related but not limited to the quality of the sample and exposition of the test to humidity
3. This kit is intended ONLY for testing of individual samples. Do not use it for testing of cadaver samples, saliva, urine or other body fluids, or pooled (mixed) blood.
4. This is a qualitative assay and the results can not be used to measure antibodies concentrations.

PRECAUTION

For professional use only

1. **This test is for *In Vitro Use only*** IVD

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2. All the waste and sample should be treated in case of transmitting disease and must be properly disinfected (autoclaving is preferred) before disposal.
3. Once taking the cassette out of the pouch, carry out your testing as early as possible (no more than 20 minutes) to avoid moisture. The nitrocellulose membrane can absorb water, which can affect the test chromatography performance.
4. The performance characteristics of the test depend on sample quality and preparation. For strong reactive samples, the red line (corresponding to the Test Zone (T)) may appear in 3-5 minutes after sample loading, but for weak reactive samples, the red line may appear in 15 minutes. To obtain accurate assay results, the test results must be read within 30 minutes. Results obtained after 30 minutes can lead to incorrect interpretation.

Remove the protective cap

Push firmly onto the chosen site on the finger

5. Make sure that the test is not expired (EXP Date indicated on the kit box).
6. If automatic pipette is used, calibrate it frequently to assure the accuracy of dispensing. Use different disposal pipette tips for each specimen in order to avoid cross-contaminations.
7. Do not modify the test procedure.
8. Do not reuse the test cassettes. Autoclave before disposal.
9. A test giving an invalid result should be repeated.
10. Blood that has been chemically treated, heated, diluted, or otherwise modified may give inaccurate results.
11. The test kit can be stored at temperatures between 2 to 30ºC in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat.
12. This test can be stored at room temperature (2-30 ºC do not freeze!) for 18 months from the date of manufacture (see label on strip pouch). Use immediately after opening.

ISO 13485
ISO 9001

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Date Adopted	Cat # 177575-1-12
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Revision C Date: 2015-08-15	

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