HIV-1/2 Rapid Test
Diagnostic Test for Detecting HIV Infection

Name and Intended Use

HIV-1/2 Rapid Test is a visual, qualitative immunoassay for in vitro detection of antibodies to Human Immunodeficiency virus types 1 and 2 (HIV-1 and HIV-2). The test is intended as an aid to diagnosis of HIV infection.

Summary and Explanation of the Test

Human immunodeficiency virus type 1 and 2 (HIV 1+2) are enveloped single strand RNA virus that cause acquired immunodeficiency syndrome (AIDS). HIV-1 has been isolated from patients with AIDS and AIDS-related complex, and from healthy individuals with high risk for developing AIDS. HIV-2 has been isolated from West African AIDS patients and from seropositive asymptomatic individuals.

Both HIV-1 and HIV-2 virus elicit strong immune responses, including the production of anti-virus antibodies. Presence of specific anti HIV-1 and/or anti HIV-2 virus antibodies in blood, serum, or plasma indicates exposure of an individual to the HIV-1 and/or HIV-2 virus, and is of great value in clinical diagnosis.

Biological Principles of the Procedure

HIV-1/2 Rapid Test is a recombinant antigen based, two-sided lateral flow immunoassay. It is composed of a pad containing red colloidal gold particles coated with recombinant HIV-1 antigens gp41/120 and recombinant HIV-2 antigen gp36. A second area of the test strip has a membrane that is coated with the same HIV-1 and HIV-2 antigens. During the test, if HIV antibodies are present in the sample they bind to the antigens on the colored particles. The complex of antibody-antigen then migrates through the membrane and is captured by the recombinant antigens immobilized in the test region. This captured complex shows up as a pink to red line.

Absence of a line in the test region (T) suggests a negative result. The test contains an internal control in the control region (C) that should always show up as a pink-red line regardless of the test line result.

Materials Provided

HIV-1/2 Rapid Test contains the following components to perform the assay:

1. Test Device (cassette)
2. Sample loop (5 microliter)
3. Antiseptic pad
4. Assay buffer
5. Instruction manual
6. Lancet

Accessories (required, but not provided):

1. Micropipette (if loop is not used)
2. Timer

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Storage and Stability

The test devices are sealed in a moisture-proof foil laminate pouch, containing desiccant. These should be stored in the coolest and driest area available, preferably at 4-30°C. The kit has a shelf life of 15 months from the date of manufacture. The devices should not be frozen and must be protected from exposure to humidity; once a pouch is opened, the device should be used within one hour.

Precautions

To obtain reproducible results, the following instructions must be followed:

1. For *in vitro* diagnostic use only with whole blood, serum or plasma samples.
2. Use disposable gloves while handling potentially infectious material and performing the assay.
3. Do not use the kit beyond the expiration date.
4. Do not eat, smoke, or drink while handling specimens.
5. Do not combine reagents from different batch numbers as the components are optimized for individual batch to give best results.
6. Clean up spills thoroughly using an appropriate disinfectant.
7. Do not open the foil pouch until it attains room temperature to prevent formation of condensation.
8. For best results, follow the test procedure and storage instructions strictly.

Specimen Collection and Storage

1. Collect whole blood in a clean container by venipuncture. Use either plain tubes for serum or tubes containing anti-coagulant (EDTA, citrate or heparin) for plasma. Separate the serum or plasma. If samples are not immediately tested, they should be stored at 4-8°C for not more than 2 weeks.
2. Fresh blood from a finger prick may also be used as a test sample. The sample application area of the device will separate the cells from the plasma.

Test Procedure

1. Bring the complete kit and sample to be tested to room temperature prior to testing. Once the device pouch is opened, it must be used within one hour.
2. Using the sample loop provided, or a suitable micropipette, place two loops of blood (10 microliters) or one loop (5 microliters) of serum/plasma into the sample window of the device. If using the loop, press gently against the bottom of the sample window, twist slightly, and allow the sample to flow out of the loop.
3. Add 3-4 drops of assay buffer to the buffer window as shown below.
4. The buffer will rehydrate the red colloidal gold conjugate, which will mix with the sample and flow onto the membrane. After 10-15 minutes all the pink color from the conjugate will clear from the membrane except for test and controls lines which form. The result of the test can then be read.

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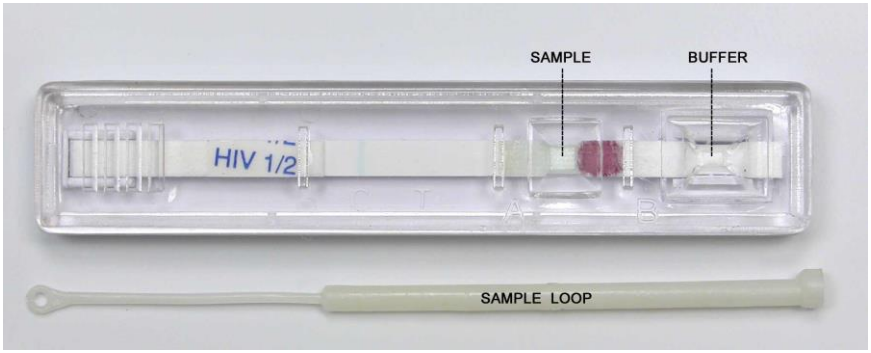

Interpretation of Results

As shown below, a reactive test shows as two or three colored lines, one in the control area (C), and one or two in the test areas (1 and/or 2). The test should be considered reactive if any visible line is evident in the test areas, even if very faint. A non-reactive test shows only one colored line in the control area. If no lines are visible, the test is invalid.

Performance Characteristics

The test can detect sample 3 of the Biorad HIV seroconversion panel RP-029. This sensitivity is equivalent or better than HIV ELISA tests as described in the Biorad literature. The test has been evaluated with positive and negative clinical samples with results as follows:

Sample	Total Number	Positive	Negative	Sensitivity (%)	Specificity (%)
HIV Negative	150	0	150	--	100%
HIV-1 Positive	80	80	0	100%	--
HIV-2 Positive	12	12	0	100%	--

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Limitations and Interferences

1. The test procedure, precautions and interpretation of results for the test must be followed strictly.
2. The test is a qualitative screening assay and is not for quantitative determination of antibodies to HIV 1 or 2. There is no meaning attributed to line color intensity or width.
3. **This is only a screening test.** The test does not rule out HIV infection because the antibodies may not be present in sufficient quantity to be detected at a very early stage of infection.
4. The results obtained must be confirmed by other diagnostic procedures and clinical data.

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