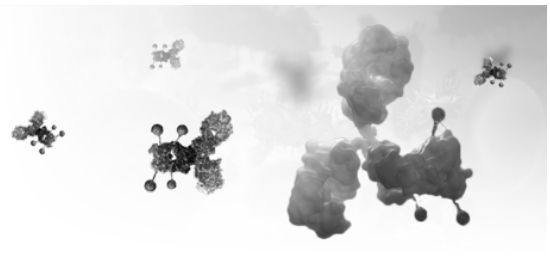


Multispot HIV-1/HIV-2 Rapid Test (DEIA-H017)

This product is for research use only and is not intended for diagnostic use.

PRODUCT INFORMATION

Size 50T

Intended Use

The Multispot HIV-1/HIV-2 Rapid Test is a single use qualitative immunoassay to detect and differentiate circulating antibodies to Human Immunodefi ciency Virus Types 1 and 2 (HIV-1, HIV-2) in fresh or frozen human serum and plasma. This rapid HIV-1/HIV-2 test kit is intended as an aid in the diagnosis of infection with HIV-1 and/or HIV-2 in fresh or frozen human serum or plasma. This test is suitable for use in multi-test algorithms designed for statistical validation of rapid HIV test results or as part of an HIV-1/HIV-2 diagnostic testing algorithm that includes differentiation of HIV-1 and HIV-2 antibodies.

General Description

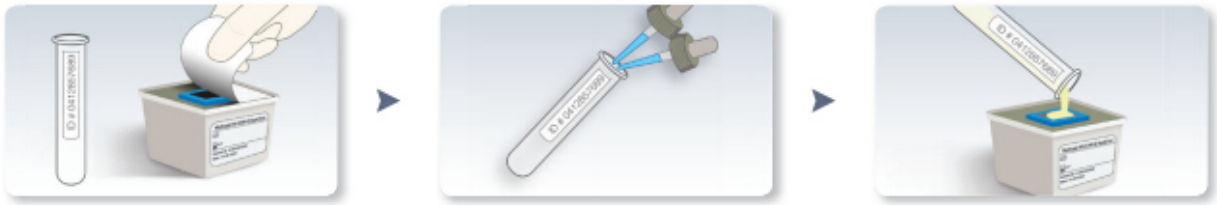
The human immunodeficiency virus (HIV) is a lentivirus (a subgroup of retrovirus) that causes the acquired immunodeficiency syndrome (AIDS), a condition in humans in which progressive failure of the immune system allows life-threatening opportunistic infections and cancers to thrive. Without treatment, average survival time after infection with HIV is estimated to be 9 to 11 years, depending on the HIV subtype. Infection with HIV occurs by the transfer of blood, semen, vaginal fluid, pre-ejaculate, or breast milk. Within these bodily fluids, HIV is present as both free virus particles and virus within infected immune cells.

HIV can be divided into two major types, HIV type 1 (HIV-1) and HIV type 2 (HIV-2). HIV-1 is related to viruses found in chimpanzees and gorillas living in western Africa, while HIV-2 viruses are related to viruses found in the endangered west African primate sooty mangabey. HIV-1 viruses may be further divided into groups. The HIV-1 group M viruses predominate and are responsible for the AIDS pandemic. Group M can be further subdivided into subtypes based on genetic sequence data. Some of the subtypes are known to be more virulent or are resistant to different medications. Likewise, HIV-2 viruses are thought to be less virulent and transmissible than HIV-1 M group viruses, although HIV-2 is known to cause AIDS.

Assay Procedure

Refer to the Package Insert for detailed procedure instructions.

45-1 Ramsey Road, Shirley, NY 11967, USA
Email: info@creative-diagnostics.com
Tel: 1-631-624-4882 Fax: 1-631-938-8221



Remove foil. Label cartridge and specimen or control test tubes.

Add 2 dropperfuls (300 µL) of specimen diluent to each test tube Add 1 drop (30 µL) specimen or control. Mix well.

Pour specimen into the prefilter. Wait 2 min. Remove and discard prefilter.

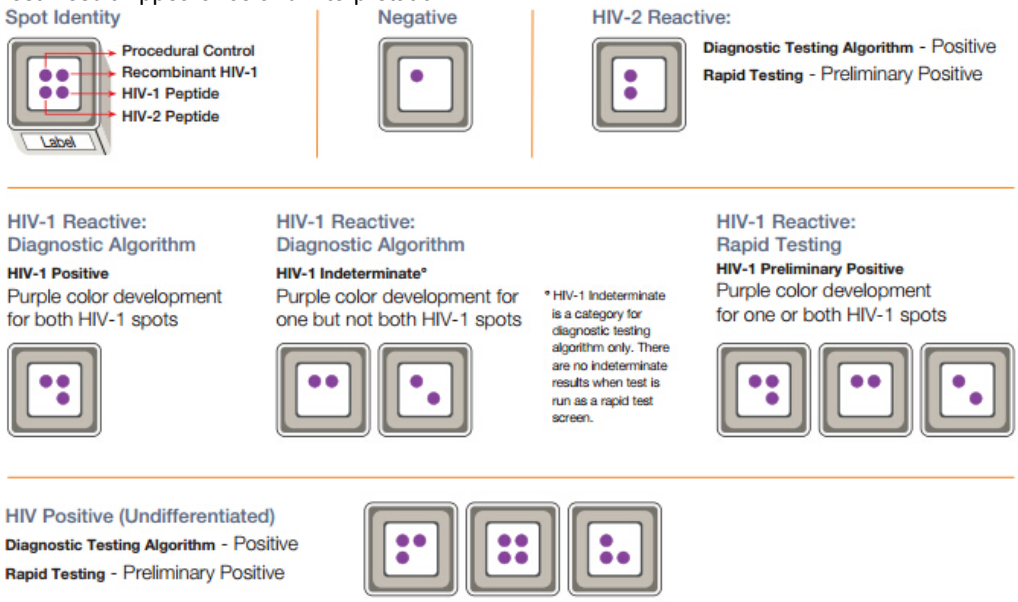
Fill cartridge with wash solution and let absorb. Add 3 drops conjugate. Wait 2 min.

Fill with wash solution and let absorb. Repeat. Add 3 drops development reagent. Wait 5 min.

Fill with stop solution. Allow to absorb and read results.

Interpretation Of Results

Test Result Appearance and Interpretation



A dilutional procedure is used to differentiate samples that have purple color development in both HIV-1 and HIV-2 spots. After dilutional testing, if the dual reactivity does not disappear or both spots become nonreactive at the same dilution, the specimen should be reported as Undifferentiated. Refer to the Package Insert for detailed instructions.

If no color develops in the Procedural Control Spot, the results are invalid.

Limitations

1. Sale of Multispot HIV-1/HIV-2 Rapid Test is restricted to clinical laboratories that have an adequate quality assurance program, including planned systematic activities to provide adequate confi dence that requirements for quality will be met and where there is assurance that operators will receive and use the instructional materials.

2. The Multispot HIV-1/HIV-2 Rapid Test is approved for use only by an agent of a clinical laboratory.

3. Test subjects must receive the "Subject Information Notice" prior to specimen collection, and

appropriate information when test results are provided, unless this test is used as part of a multi-test diagnostic algorithm.

4. The Multispot HIV-1/HIV-2 Rapid Test is not approved for use to screen blood, plasma, cell, or tissue donors.