Multispot HIV-1/HIV-2 Rapid Test

The Clear Choice to See HIV-1 and HIV-2 — Separately
Multispot HIV-1/HIV-2 Rapid Test

**Trusted Interpretation**

- HIV-1 Positive
- HIV-2 Positive
- HIV-1 Indeterminate  
  (Applicable to Diagnostic Testing Algorithm only and not to Rapid Testing Criteria)
- HIV Positive  
  (Undifferentiated)

**The only HIV antibody differentiation test for use in a Diagnostic Testing Algorithm**

*CLSI M53-A (Vol 31 No 13)*
HIV-1 Indeterminate is a category for diagnostic testing algorithm only. There are no indeterminate results when test is run as a rapid test screen.

**Test Result Appearance and Interpretation**

<table>
<thead>
<tr>
<th>Spot Identity</th>
<th>Negative</th>
<th>HIV-2 Reactive: Diagnostic Testing Algorithm - Positive</th>
<th>HIV-1 Reactive: Diagnostic Testing Algorithm - Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedural Control</td>
<td>Recombinant HIV-1</td>
<td>Recombinant HIV-1</td>
<td>Recombinant HIV-1</td>
</tr>
<tr>
<td>HIV-1 Peptide</td>
<td>HIV-1 Peptide</td>
<td>HIV-1 Peptide</td>
<td>HIV-1 Peptide</td>
</tr>
</tbody>
</table>

**HIV-1 Reactive:**
- **Diagnostic Algorithm**
  - HIV-1 Positive: Purple color development for both HIV-1 spots
  - HIV-1 Indeterminate*: Purple color development for one but not both HIV-1 spots

**HIV-2 Reactive:**
- **Diagnostic Testing Algorithm** - Positive
- **Rapid Testing** - Preliminary Positive

**HIV Positive (Undifferentiated)**
- **Diagnostic Testing Algorithm** - Positive
- **Rapid Testing** - Preliminary Positive

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.

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

**Multispot HIV-1/HIV-2 Rapid Test**

**INTENDED USE:**
The Multispot HIV-1/HIV-2 Rapid Test is a single use qualitative immunoassay to detect and differentiate circulating antibodies to Human Immunodeficiency 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.

**RESTRICTIONS:**
- 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 confidence that requirements for quality will be met and where there is assurance that operators will receive and use the instructional materials.
- The Multispot HIV-1/HIV-2 Rapid Test is approved for use only by an agent of a clinical laboratory.
- 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.
- The Multispot HIV-1/HIV-2 Rapid Test is not approved for use to screen blood, plasma, cell, or tissue donors.
Multispot HIV-1/HIV-2 Rapid Test

**Procedure**
(Refer to the Package Insert for detailed procedure instructions.)

Remove foil. Label cartridge and specimen or control test tubes.  
Add 2 dropperfuls (300 µL) of specimen diluent to each test tube.  
Pour specimen into the prefILTER.  
Add 1 drop (30 µL) specimen or control. Mix well.  
Wait 2 min. Remove and discard prefILTER.  
Add 2 dropperfuls (300 µL) of specimen diluent to each test tube.  
Wait 2 min. Remove and discard prefILTER.  
Add 1 drop (30 µL) specimen or control. Mix well.  
Fill 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.

**Ordering Information**

<table>
<thead>
<tr>
<th>Catalog No.</th>
<th>Description</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>25228</td>
<td>Multispot HIV-1/HIV-2 Rapid Test*</td>
<td>50 tests</td>
</tr>
</tbody>
</table>

* Only Available in the US.