Geenius HIV 1/2 Supplemental Assay
Band Identification with HIV 1/2 Differentiation

- **Band 1**
  - gp36 (HIV-2, envelope peptide)
  - HIV-2 ENV

- **Band 2**
  - gp140 (HIV-2, envelope peptides)
  - HIV-2 ENV

- **Band 3**
  - p31 (HIV-1, polymerase peptide)
  - HIV-1 POL

- **Band 4**
  - gp160 (HIV-1, envelope recombinant protein)
  - HIV-1 ENV

- **Band 5**
  - p24 (HIV-1, core recombinant protein)
  - HIV-1 GAG

- **Band 6**
  - gp41 (Group M and O)
  - HIV-1 ENV

- **Control Band**
  - Protein A
Dispense 15 µl of whole blood or 5 µl of serum/plasma into Well 1

Add 2 drops of buffer into Well 1

Wait 5 to 7 minutes after adding drops

Add 5 drops of buffer into Well 2

Wait 15 to 20 minutes after adding drops

Read, interpret and report results

Simple, Fast, and Accurate
Automated Interpretation

Proprietary software used for results interpretation.
- Bands read by Geenius Reader
- Band interpretation by validated software
### Traceability

**Printable report with detailed results and patient information.**

- Unique 2D barcode on each cassette
- Positive identification of controls and patients
- Results report with picture of cassette

---

**Geenius HIV 1/2**

**Sample ID:** Panel4-2  
**Cassette ID:** 198003729841  
**Kit Lot - Exp. Date:** 01/11/2021  
**Order date:** 07/22/2019 08:26:43  
**Analysis date:** 07/22/2019 08:26:44  
**Test run by:** Supervisor -  
**Test version:** 2.0-US  
**Rule(s):** HIV-1 Criteria - HIV-2 Criteria

**Reader S/N:** DP7K105905  
**Geenius version:** 2.0.203.002  
**Last Calibration:** 07/22/2019 07:49:57

**Controls**

- **Lot number:** PC18H0023200807  
- **Last run on:** 07/22/2019 07:18:29  
- **Lot number:** NC18H0023200806  
- **Last run on:** 07/22/2019 07:19:14

**Interpretation**

**Interpretation type:** Automatic

**Band analysis:**

<table>
<thead>
<tr>
<th>#</th>
<th>Name</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>gp36</td>
<td>Absent</td>
</tr>
<tr>
<td>2</td>
<td>gp140</td>
<td>Absent</td>
</tr>
<tr>
<td>3</td>
<td>p31</td>
<td>Absent</td>
</tr>
<tr>
<td>4</td>
<td>gp160</td>
<td>Present</td>
</tr>
<tr>
<td>5</td>
<td>p24</td>
<td>Absent</td>
</tr>
<tr>
<td>6</td>
<td>gp41</td>
<td>Present</td>
</tr>
<tr>
<td>7</td>
<td>CTRL</td>
<td>Present</td>
</tr>
</tbody>
</table>

**HIV-1 Result:** HIV-1 Ab reactive  
**HIV-2 Result:** HIV-2 Ab nonreactive

**Conclusion:** HIV-1 POSITIVE (HIV-1 Ab reactive/HIV-2 Ab nonreactive)

**Status:** Validated  
**by:** Supervisor -
Intended Use

The Bio-Rad Geenius HIV 1/2 Supplemental Assay is a single-use immunochromatographic assay for the confirmation and differentiation of individual antibodies to Human Immunodeficiency Virus Types 1 and 2 (HIV-1 and HIV-2) in fingerstick whole blood, venous whole blood, serum, or plasma samples (EDTA, heparin, and sodium citrate).

The Geenius HIV 1/2 Supplemental Assay is intended for use as an additional, more specific test to confirm the presence of antibodies to HIV-1 and HIV-2 for specimens found to be repeatedly reactive by diagnostic screening procedures or by an FDA licensed HIV-1/HIV-2 blood donor screening test.

For diagnostic testing the assay may also be used to confirm the presence of antibodies to HIV-1 and/or HIV-2 in pediatric subjects (i.e. children as young as 2 years of age).

The results of the Geenius HIV 1/2 Supplemental Assay must be read and interpreted only by the Geenius Reader with dedicated software.

Restrictions

■ Sale of the Geenius HIV 1/2 Supplemental Assay for diagnostic testing is restricted to clinical testing 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 Geenius HIV 1/2 Supplemental Assay is approved for diagnostic testing only by an agent of a clinical testing laboratory.

Ordering Information

<table>
<thead>
<tr>
<th>Catalog No.</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>72461</td>
<td>Geenius HIV 1/2 Supplemental Assay for Diagnostic Testing</td>
</tr>
<tr>
<td>72480</td>
<td>Geenius HIV 1/2 Supplemental Assay for Donor Testing</td>
</tr>
<tr>
<td>72339</td>
<td>Geenius HIV 1/2 Supplemental Controls for Diagnostic and Donor Testing</td>
</tr>
</tbody>
</table>

BIO-RAD is a trademark of Bio-Rad Laboratories, Inc.

GEENIUS is a trademark of Bio-Rad Europe, GmbH in certain jurisdictions.