DPP® HIV 1/2 Assay

- Oral fluid and blood rapid HIV test
- Excellent sensitivity and specificity\(^1\)
- Ready-to-use reagents
- Technology prevents issues with “over collection” of oral fluid
- 24-month open vial stability for quality controls
  - 50 control runs per vial

**Oral Fluid and Blood Assay**

**Distinct Test and Control Lines**

**Soft Foam Tip**

**DPP® Sample Tainer® specimen collection bottle:**
A safe, closed system for handling potentially infectious blood and oral fluid samples.

**NEXT GENERATION DPP™**

**DPP® HIV 1/2: Earlier Detection Than Leading POC HIV Tests**

<table>
<thead>
<tr>
<th>RNA nucleic acid test</th>
<th>DPP® HIV 1/2</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td></td>
</tr>
<tr>
<td>175</td>
<td></td>
</tr>
<tr>
<td>20.3</td>
<td></td>
</tr>
<tr>
<td>21.6</td>
<td></td>
</tr>
<tr>
<td>23.7</td>
<td></td>
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</tbody>
</table>

Detection in days after HIV-1 RNA detection

*adapted from: http://www.cdc.gov/hiv/pdf/testing_Advantages&Disadvantages.pdf

Clearview is a trademark of the Alere group of companies; Uni-Gold and Recombigen are trademarks of Trinity Biotech; Advance is a trademark of OraSure Technologies, Inc.

**Manufactured in the USA**

FDA approved
CLIA waived for oral fluid, fingerstick and venous whole blood

\(^1\) Sensitivity: 99.9% Whole Blood/Plasma/Serum; 99.8% Fingerstick; 98.9%* Oral Fluid
Specificity: 100% Fingerstick; 99.9% Oral Fluid/Whole Blood/Plasma/Serum

* 98.9% (953/964), 7 false negative individuals were previously known test positives on Highly Active Anti-Retroviral Therapy (HAART). An Individual infected with HIV who is receiving highly active antiretroviral therapy (HAART) may produce false negative results.
Administering Test*

1. **OBTAIN** oral fluid sample by swabbing around the outer gums for a minimum of 30 seconds.

   Or **OBTAIN** a blood sample with sample loop.

   **At least 30 Seconds**

   **OR**

   **INSERT** the oral fluid swab into the bottom of the SampleTainer® bottle. **SNAP & DETACH** leaving swab in vial. **REPLACE** black cap. **SHAKE** SampleTainer® bottle 10 sec.

   Or **INSERT** the sample loop with collected blood sample into the bottom of the SampleTainer® bottle. **BEND & TWIST** to detach from loop end remaining in vial. **REPLACE** black cap. **SHAKE** SampleTainer® bottle 10 sec.

   **OR**

   **ADD** 4 drops of running buffer (green cap) to buffer well 2. **Blood**: Read result at 10 minutes after the addition of the running buffer to well 2; do not read results after 25 minutes. **Oral fluid**: read result between 25-40 minutes. Wait 40 minutes to confirm negative.

   **Wait 5 minutes.**

   **ADD** 2 drops into the Sample + Buffer well 1.

   **WAIT** 5 minutes. **OR**

   **ADD** 4 drops of running buffer (green cap) to buffer well 2. **Blood**: Read result at 10 minutes after the addition of the running buffer to well 2; do not read results after 25 minutes. **Oral fluid**: read result between 25-40 minutes. Wait 40 minutes to confirm negative.

   **OR**

   **REMOVE** the black cap. **ADD** 2 drops into the Sample + Buffer well 1. **WAIT** 5 minutes.

Interpretation of Results:

<table>
<thead>
<tr>
<th>Description</th>
<th>Contents</th>
<th>Catalog Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>DPP® HIV 1/2 Assay, FDA Approved</td>
<td>20 Individually Pouched DPP HIV 1/2 Test Devices with dessicant pouch 1 Quick Reference Instructions (for CLIA Waived) 20 Copies of Subject Information Notice 20 Oral Fluid Swabs 20 Disposable 10µL Sample Loops 20 DPP HIV SampleTainer® Bottle – BLACK Cap 1 DPP HIV Running Buffer – GREEN Cap 1 Product Insert for the DPP HIV 1/2 Assay</td>
<td>65-9500-0</td>
</tr>
<tr>
<td>DPP® HIV 1/2 Rapid Test Control Pack</td>
<td>1 pack contains: 1 HIV-1 Reactive Control 0.5 mL 1 HIV-2 Reactive Control 0.5 mL 1 HIV Nonreactive Control 0.5 mL Each kit control vial contains sufficient volume to run 50 tests</td>
<td>60-9552-0</td>
</tr>
</tbody>
</table>

* Before testing, please refer to the complete product insert provided in the test kit