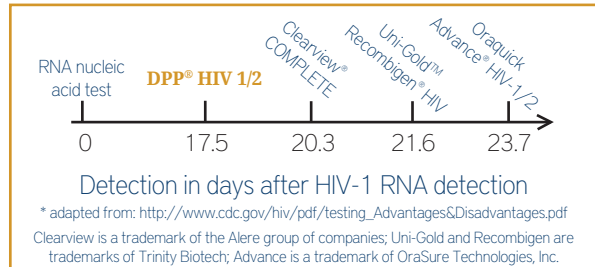


**CLIA WAIVED**

# NEXT GENERATION DPP™ DPP® HIV 1/2 Assay

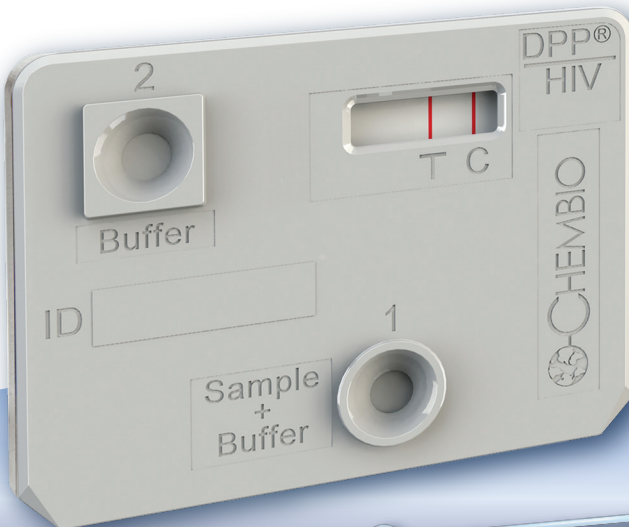
- Oral fluid and blood rapid HIV test
- Excellent sensitivity and specificity<sup>1</sup>
- Ready-to-use reagents
- Technology prevents issues with “over collection” of oral fluid
- 24-month open vial stability for quality controls
  - 50 control runs per vial

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



## Blood and Oral Fluid Assay

Distinct Test and Control Lines



Soft Foam Tip

DPP® SampleTainer® specimen collection bottle:

A safe, closed system for handling potentially infectious blood and oral fluid samples.



DIAGNOSTIC SYSTEMS, INC.

Rapid Tests for Earlier Treatment™

**Manufactured in the USA**

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

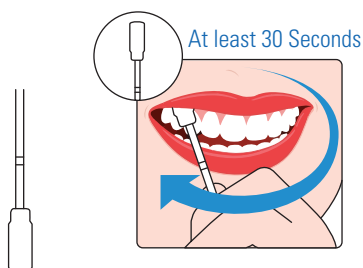
<sup>1</sup> Sensitivity: 99.9% Whole Blood/Plasma/Serum; 99.8% Fingerstick; 98.9%\* Oral Fluid  
Specificity: 100% Fingerstick; 99.9% Oral Fluid/Whole Blood/Plasma/Serum

\* 98.9% (953/964), 7 false negative individuals were previous 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.

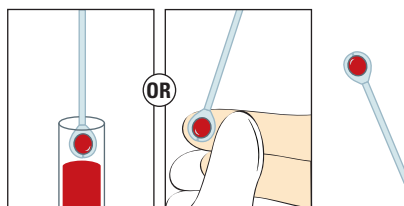
## Administering Test\*

- 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.



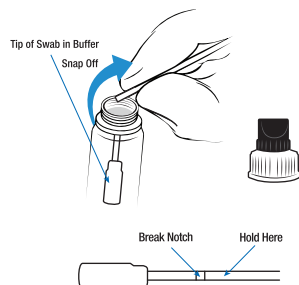
OR



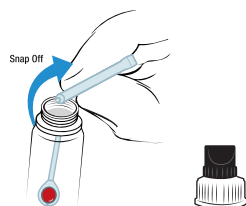
\* Before testing, please refer to the complete product insert provided in the test kit

- 2 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.

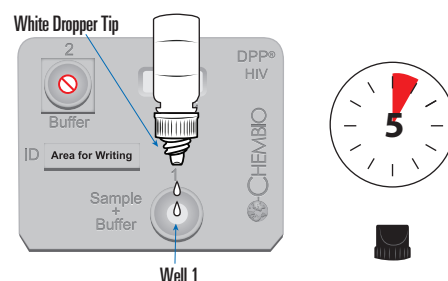
Or INSERT the sample loop with collected blood sample into the bottom of the SampleTainer® bottle. BEND & TWIST to detach from loop end remaining in vial. REPLACE black cap. SHAKE SampleTainer® bottle 10 sec.



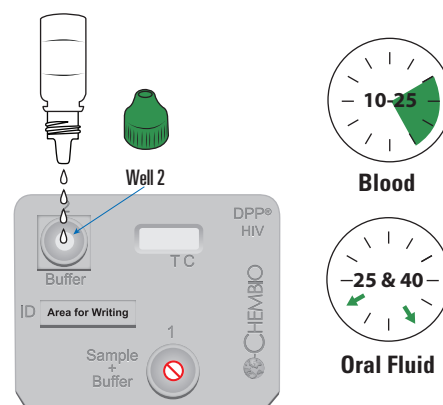
OR



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



- 4 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.



## Interpretation of Results:

NON-REACTIVE



REACTIVE



| Description                          | Contents  | Catalog Number |
|--------------------------------------|---|----------------|
| DPP® HIV 1/2 Assay, FDA Approved     | 20 Individually Pouched DPP HIV 1/2 Test Devices with dessicant pouch<br>1 Quick Reference Instructions (for CLIA Waived)<br>20 Copies of Subject Information Notice<br>20 Oral Fluid Swabs<br>20 Disposable 10µL Sample Loops<br>20 DPP HIV SampleTainer® Bottle – BLACK Cap<br>1 DPP HIV Running Buffer – GREEN Cap<br>1 Product Insert for the DPP HIV 1/2 Assay | 944104         |
| DPP® HIV 1/2 Rapid Test Control Pack | 1 pack contains:<br>- 1 HIV-1 Reactive Control 0.5 mL<br>- 1 HIV-2 Reactive Control 0.5 mL<br>- 1 HIV Nonreactive Control 0.5 mL<br>Each kit control vial contains sufficient volume to run 50 tests  | 944106         |