

# Comparative Performance of the Aptima HIV-1 RNA QuantDx Assay (Panther) with Serum and Plasma at Dual Public Health Laboratories

**Advancing HIV, STI and Viral Hepatitis Testing Conference,  
“Molecular Testing as the Second Test in the HIV Diagnostic Algorithm” (Discussion Panel)**

**March 29, 2022**



Berry Bennett, MPH  
[Berry.Bennett@FLHealth.gov](mailto:Berry.Bennett@FLHealth.gov)

Monica M Parker, PhD  
[monica.parker@health.ny.gov](mailto:monica.parker@health.ny.gov)



*Conflict of Interest statement: I do not have any financial relationship with commercial entities to disclose.*

# Objective


- A brief review of the Florida Bureau of Public Health Laboratories (BPHL) and the New York State Department of Health, Wadsworth Center testing experience with matched serum and plasma on the Aptima HIV-1 RNA QuantDx assay (Panther<sup>®</sup> system).

# Study Design

- The primary focus of this study, by both PHLs, was to perform in-house validations of the HIV-1 RNA QuantDx assay with matched plasma and serum for diagnostic use.
- Neither PHL intended to validate the HIV-1 RNA QuantDx assay with serum for routine clinical management use.
- WC and FL PHLs received separate aliquots of a customized matched serum/plasma HIV-1 RNA Positive Panel\* representing a dynamic range of HIV-1 RNA quantitative values.
- Specimens tested in singlet with the Aptima HIV-1 RNA QuantDx Assay (Panther system).
- Matched specimens received and stored frozen (-20°C) until use.

\* BioCollections Worldwide, Inc., panel #1003

# Results



Serial ID #	BioCollections Plasma Log10 cp/mL	WC plasma Log10 Value	WC serum Log10 Value	WC plasma - WC serum Log10 diff	WC plasma - BC plasma Log10 diff	WC/FL Qual Plasma	WC/FL Qual Serum	FL plasma Log10 value	FL serum Log10 value	FL plasma - FL serum Log10 diff	FL plasma - BC plasma Log10 diff
11563	< 1.47	<1.47	<1.47			R/R	R/R	<1.47	<1.47		
11564	< 1.47	1.63	<1.47			R/R	R/R	1.48	<1.47		
11565	< 1.47	<1.47	<1.47			R/R	R/R	1.71	<1.47		
11566	< 1.47	1.62	<1.47			R/R	R/NR	1.51	TND		
11567	< 1.47	<1.47	<1.47			R/R	R/NR	<1.47	TND		
11568	2.86	2.73	2.72	0.01	-0.13	R/R	R/R	2.87	2.78	0.09	0.01
11569	2.98	2.77	2.60	0.17	-0.21	R/R	R/R	2.89	2.71	0.18	-0.09
11570	2.72	2.24	2.57	-0.33	-0.48	R/R	R/R	2.41	2.63	-0.22	-0.31
11571	2.97	2.90	2.35	0.55	-0.07	R/R	R/R	2.92	2.44	0.48	-0.05
11572	2.24	2.38	2.19	0.19	0.14	R/R	R/R	2.44	2.26	0.18	0.20
11573	4.93	4.04	4.85	-0.81	-0.89	R/R	R/R	4.94	5.17	-0.23	0.01
11574	4.17	4.14	4.00	0.14	-0.03	R/R	R/R	4.18	4.05	0.13	0.01
11575	4.95	4.82	4.74	0.08	-0.13	R/R	R/R	4.89	4.81	0.08	-0.06
11576	4.86	4.32	5.05	-0.73	-0.54	R/R	R/R	4.91	5.00	-0.09	0.05
11577	4.27	3.85	3.63	0.22	-0.42	R/R	R/R	4.28	4.31	-0.03	0.01
11578	5.66					NA/R	NA/R	5.60	5.11	0.49	-0.06
11579	5.61	5.72	5.35	0.37	0.11	R/R	R/R	5.66	5.27	0.39	0.05
11580	5.98					NA/R	NA/R	5.84	5.54	0.30	-0.14
11581	5.66					NA/R	NA/R	5.64	5.28	0.36	-0.02
11582	5.2	5.25	5.11	0.14	0.05	R/R	R/R	5.18	4.95	0.23	-0.02

WC = Wadsworth Center Public Health Laboratory FL = Florida Bureau of Public Health Laboratories  
 BC = BioCollections Worldwide, Inc

R = Reactive, NR = Nonreactive, NA = data not available, TND = Target (RNA) not detected

# Results

## Qualitative

- 100% (37/37) concordant reactive for plasma per the HIV-1 RNA QuantDx IFU's "Diagnostic Qualitative Interpretation".
- 95% (35/37) concordant reactive for serum per the HIV-1 RNA QuantDx IFU's "Diagnostic Qualitative Interpretation". (TND results are interpreted as non-reactive for HIV-1 RNA).

## Quantitative

- 88.9% (24/27) agreement between matched plasma and serum in Log10 differences (<0.5 log10 difference clinical margin).
- 92.6% (25/27) agreement between WC/FL plasma and BC plasma in Log10 differences (<0.5 log10 difference clinical margin).

# Discussion & Limitations

- Despite an 88.9% agreement between HIV-1 RNA QuantDx quantitative values with matched plasma and serum, our consensus is that more data is needed to support a serum specimen for the following applications,
  - Routine use as a laboratory marker to monitor the effects of ART.
  - PrEP entry and routine monitoring for early HIV infection.
- The BioCollections matched serum and plasma HIV-1 RNA Positive Panel did not include Aptima HIV-1 RNA QT assay results for serum.

# Acknowledgements

## FL Bureau of Public Health Laboratories

Sally Fordan  
Jessica Ribbing  
Susanne Crowe  
Mary Ritchie

## NYSDOH Wadsworth Center

Tim Sullivan  
Jean Rock

## Hologic, Inc

Tiffany Clarke  
Melissa Love  
Scott Hauenstein

## BioCollections Worldwide, Inc

# Thank you & Questions

## Recommended resources



INFECTIOUS DISEASES

DECEMBER 2021

### Use and Interpretation of Quantitative HIV-1 RNA Test Results: Guidance for Laboratories

THIS DOCUMENT OUTLINES THE IMPORTANCE OF ACCURATELY REPORTING RESULTS FROM QUANTITATIVE HIV-1 RNA ASSAYS.

[www.aphl.org/hiv](http://www.aphl.org/hiv)



Updated version  
January 2019



[www.aphl.org/hiv](http://www.aphl.org/hiv)