

## anti-HIV-1 Antibodies in Dried Blood Spots Proficiency Testing Program (HIVPT)

### 2017 Quarter 2 May

#### Introduction

This report is the summary of data reported within the specified period for Quarter 2, 2017, anti-HIV-1 Antibodies in dried blood spots (DBS) PT event. It is distributed to all participants, state laboratory directors, and program colleagues by request. The tables within this report provide certification profiles and distribution information for the HIVPT specimen panel, participant result information for screening methods, confirmatory methods, and final interpretations. An evaluation of your reported data is attached to this summary.

#### Certification of PT Specimens

Method and laboratory performance are evaluated by challenging participants with DBS specimens representing HIV- negative and positive serostatuses. Anti-HIV-1 Antibody screening and confirmatory tests should identify all HIV-positive specimens, regardless of subtype. Expected screening and confirmatory results, and final clinical assessments, are provided in Table 1.

Table 1. Expected Results -EIA (OD), Western Blot (Band Detection) and Final Interpretation

Specimen	EIA—Avioq	Western Blot—Genetic Systems HIV-1 WB (Bio-Rad)									Final Interpretation
	OD	gp160	gp120	p65	P55/51	gp41	p40	p31	p24	p18	
21741	0.068	N	N	N	N	WP	N	N	N	N	Non-reactive
21742	0.118	N	N	N	N	WP	N	N	N	N	Non-reactive
21743	2.974	P	P	P	P	P	WP	P	P	N	Reactive
21744	0.092	N	N	N	N	WP	N	N	N	N	Non-reactive
21745	1.726	P	WP	WP	P	WP	P	P	P	WP	Reactive

## Distribution of PT Specimens

On April 3, 2017 a PT panel of five individual DBS matrix specimens was distributed to 13 domestic laboratories and 14 international laboratories.

## Participant Results

### ◆ Screening Data

We received data reports from 23 of the 27 participating laboratories by the designated data reporting deadline. Each participant was asked to analyze the specimens for anti-HIV-1 Antibodies with the assay schemes they routinely use. Data submission must include the screening results, any confirmatory results performed based on presumptive positive screening results, and the analytic methods used for all testing.

Table 2 shows the number of laboratories using enzyme immunoassay (EIA) screening methods/kits both for the primary and secondary screens. Table 3 provides the overall statistics for the screening EIA methods where  $N \geq 3$ .

Table 2. Number of EIA Screening Methods Reported; Includes Primary and Secondary Methods

Method	Kit Source	Primary *	Secondary
11	In House	1	0
27	Tecnosuma (Cuba) UMELISA HIV 1+2	3	0
40	Avioq HIV-1 Microeleisa Systems	10	8
41	Bio-Rad HIV-1/HIV-2 plus O EIA	1	1
43	Murex® HIV-1.2.O. Diasorin	2	2
12	Other	2	0
<i>Total</i>		19	10

\*Four laboratories did not report EIA data and reported final interpretations based on a Western Blot confirmatory test.

Table 3. Over Statistics Screening Methods ( $N \geq 3$ )\*

Method	Statistic	Specimen				
		21741	21742	21743	21744	21745
Avioq HIV-1 Microelisa System (N=10)	Mean	0.108	0.119	2.823	0.163	1.739
	SD	0.031	0.030	0.295	0.067	0.424
	%CV	28.6	24.9	10.4	41.3	24.4

\*Statistics not available for the Tecnosuma method due to a data reporting discrepancy.

## ◆ Confirmatory Data

Sixteen laboratories reported using Western Blot (WB) antibody analysis as either a screening or confirmatory method in the detection of anti-HIV-1 antibodies. Table 4 shows the number of laboratories using each WB kit source. Table 5 shows the Reported Frequency of Bands by WB for each of the PT specimens that tested positive for their screening analysis.

Table 4. Number of Confirmatory Methods Reported

Method Code	Kit Source	Total Participants
16	Genetic Systems HIV-1 WB Kit (Bio-Rad)	10
32	Cambridge Biotech HIV-1 WB Kit (Maxim)	3
35	OraSure HIV-1 WB Kit	0
36	New LAV Blot I (Bio-Rad)	1
37	Genelab Diagnostics HIV Blot Kit	1
42	MP Diagnostics HIV Blot 2.2	1
<i>Total</i>		16

Table 5. Frequency of WB Bands for Reactive Specimens (All Methods)

Total # of Labs (16)		Number of Laboratories Finding Reactive Bands								
Specimen	Interpretation	gp160	gp120	p66	p55	p51	gp41	p31	p24	p18
Specimen 21743	Positive	16	15	15	13	15	1	16	14	2
	Weak Positive	0	1	0	2	0	4	0	2	3
	Negative	0	0	1	1	1	6	0	0	9
	Indeterminate	0	0	0	0	0	0	0	0	2
Specimen 21745	Positive	16	5	7	12	7	6	8	16	1
	Weak Positive	0	5	5	2	4	1	3	0	6
	Negative	0	6	4	2	4	4	5	0	8
	Indeterminate	0	0	0	0	1	0	0	0	1

## ◆ Final Interpretations

A final interpretation for each specimen must be submitted to receive an evaluation. Table 6 provides the frequency of all participant interpretations.

Table 6. Frequency Distribution: Outcome of Final Interpretations (23 Laboratories)

Specimen Number	Expected Value	Non-reactive	Reactive
21741	Non-reactive	23	0
21742	Non-reactive	23	0
21743	Reactive	0	23
21744	Non-reactive	22	1
21745	Reactive	0	23

## Evaluations

Overall, participants reported one False-positive and no False-negative results.

## Future Shipments

The Newborn Screening Quality Assurance Program will ship next quarter's PT specimens for HIVPT on July 10, 2017.

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The content of this report may also be located on our website at:

[http://www.cdc.gov/labstandards/nsqap\\_reports.html](http://www.cdc.gov/labstandards/nsqap_reports.html)

**This program is co-sponsored by the Centers for Disease Control and Prevention (CDC) and  
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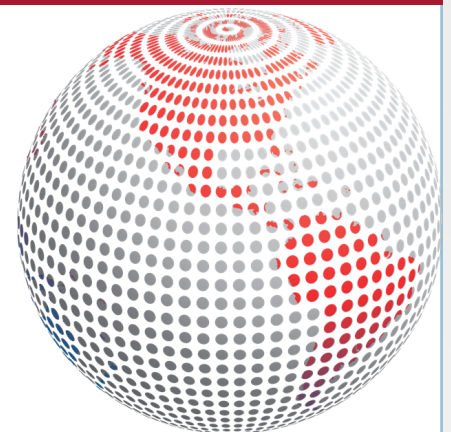
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