Newborn Screening Quality Assurance Program

Quarterly Report

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

November 4, 2017

Introduction

This report is the summary of data reported within the specified period for Quarter 4, 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	
41741	0.118	N	N	N	N	N	N	N	N	N	N
41742	0.095	N	N	N	N	N	N	N	N	N	N
41743	0.092	N	N	N	N	WP	N	N	N	N	N
41744	1.726	P	WP	WP	P	WP	P	WP	P	WP	R
41745	0.099	N	N	N	N	N	N	N	N	N	N

Distribution of PT Specimens

On October 2, 2017 a PT panel of five individual DBS specimens was distributed to 13 domestic laboratories and 15 international laboratories.

Participant Results

- Screening Data

We received data reports from 23 of the 28 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 methods. Table 3 provides the overall statistics for the screening EIA methods where N≥3.

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

Method Code	Kit Source	Primary *	Secondary
11	In House	1	
27	Tecnosuma (Cuba) UMELISA HIV 1+2	2	
40	Avioq HIV-1 Microeleisa Systems	9	2
41	Bio-Rad HIV-1/HIV-2 plus O EIA	1	
43	Murex® HIV-1.2.O. Diasorin	2	1
12	Other	4	3
	Total	19	6

*Three laboratories did not report EIA data and reported final interpretations based on a Western Blot confirmatory test. One lab reported EIA results but no method.

Table 3. Over Statistics Screening Methods (N≥3)

Method	Statistic	Specimen				
		41741	41742	41743	41744	41745
Avioq HIV-1 Microelisa System (N=9)	Mean	0.107	0.105	0.099	2.042	0.104
	SD	0.027	0.013	0.016	0.777	0.023
	%CV	25.120	12.715	16.003	38.060	22.123

♦ Confirmatory Data

Fifteen 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 by a primary screening method.

Table 4. Western Blot 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
36	New LAV Blot I (Bio-Rad)	1
37	Genelab Diagnostics HIV Blot Kit	1
	Total	15

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

Total # of Labs (15)		Number of Laboratories Finding Reactive Bands								
Specimen	Interpretation	gp160	gp120	p66	p55	p51	gp41	p31	p24	p18
Specimen 41744	Positive	15	8	7	13	6	8	10	15	2
	Weak Positive	0	4	5	1	6	1	3	0	7
	Negative	0	2	3	1	2	6	2	0	4
	Indeterminate	0	1	0	0	1	0	0	0	2

♦ 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 of Final Interpretations (23 Laboratories)

Specimen Number	Expected Value	Non-reactive	Reactive
41741	N	22	1
41742	N	22	1
41743	N	22	1
41744	R	0	23
41745	N	22	1

Evaluations

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

Future Shipments

The Newborn Screening Quality Assurance Program will ship next quarter's PT specimens for HIVPT in January 2018.

The content of this report may also be located on our website at:
http://www.cdc.gov/labstandards/nsqap_reports.html

This program is co-sponsored by the Centers for Disease Control and Prevention (CDC) and The Association of Public Health Laboratories (APHL)

NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

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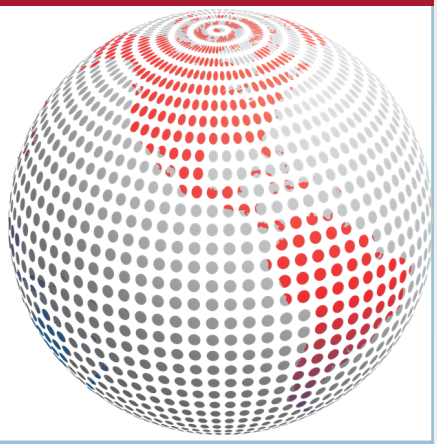

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