Newborn Screening Quality Assurance Program

Quarterly Report

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

2017 Quarter 1 February

Introduction

This report is the summary of data reported within the specified data-reporting period for Quarter 1, 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, and 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 INT.
	OD	gp160	gp120	p65	P55/51	gp41	p40	p31	p24	p18	
11741	1.600	P	WP	N	P	WP	P	N	P	P	Reactive
11742	0.068	N	N	N	N	N	N	N	N	N	Non-reactive
11743	0.118	N	N	N	N	N	N	N	N	N	Non-reactive
11744	0.092	N	N	N	N	N	N	N	N	N	Non-reactive
11745	0.095	N	N	N	N	N	N	N	N	N	Non-reactive

Distribution of PT Specimens

On January 11, 2017 a PT panel of five individual DBS matrix specimens was distributed to 14 domestic laboratories and 14 international laboratories.

Participant Results

- Screening Data

We received data reports from 23 of the 28 participating laboratories by the designated deadline date. 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 for 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≥3.

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

Method	Kit Source	Primary	Secondary
11	In House	0	0
27	Tecnosuma (Cuba) UMELISA HIV 1+2	2	0
40	Avioq HIV-1 Microeleisa Systems	11	7
41	Bio-Rad HIV-1/HIV-2 plus O EIA	1	0
43	Murex® HIV-1.2.O. Diasorin	2	2
12	Other	3	1
	Total	19	10

*Note: Three laboratories did not report EIA data and reported final interpretations based on a Western Blot confirmatory test.

Table 3. Overall statistics from the EIA method screening assay (N≥3)

Method	Statistic	Specimen				
		11741	11742	11743	11744	11745
Avioq HIV-1 Microelisa System (N=11)	Mean	1.504	0.107	0.116	0.104	0.107
	SD	0.277	0.023	0.031	0.017	0.016
	%CV	18.4	21.0	26.8	16.8	14.6

♦ Confirmatory Data

Sixteen participant 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
	Total	16

Table 5. Reported Frequency of 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 11741	Positive	14	8	2	11	6	7	0	16	13
	Weak Positive	1	6	4	2	5	1	4	0	3
	Negative	1	1	9	3	3	8	11	0	0
	Indeterminate	0	1	1	0	2	0	1	0	0

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 (22 Laboratories)

Specimen Number	Expected Value	Non-reactive	Reactive
11741	Reactive	0	22
11742	Non-reactive	22	0
11743	Non-reactive	22	0
11744	Non-reactive	22	0
11745	Non-reactive	22	0

Evaluations

Overall, participants reported no False-positive and no False-negative results. One participant submitted a data report form but did not report final interpretations and was not scored.

Future Shipments

The Newborn Screening Quality Assurance Program will ship next quarter's PT specimens for HIVPT on April 3, 2017.

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

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NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

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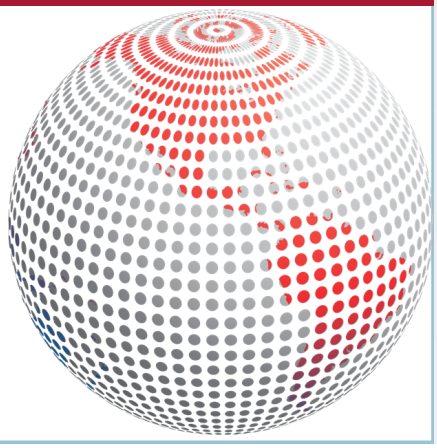

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