Newborn Screening Quality Assurance Program

Quarterly Report

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

2017 Quarter 3 August

Introduction

This report is the summary of data reported within the specified period for Quarter 3, 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	
31741	0.068	N	N	N	N	WP	N	N	N	N	Non-reactive
31742	0.118	N	N	N	N	WP	N	N	N	N	Non-reactive
31743	1.600	P	N	N	P	WP	P	N	P	P	Reactive
31744	0.092	N	N	N	N	WP	N	N	N	N	Non-reactive
31745	0.096	N	N	N	N	N	N	N	N	N	Non-reactive

Distribution of PT Specimens

On July 10, 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≥3.

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

Method	Kit Source	Primary *	Secondary
11	In House	1	
27	Tecnosuma (Cuba) UMELISA HIV 1+2	2	
40	Avioq HIV-1 Microeleisa Systems	8	1
41	Bio-Rad HIV-1/HIV-2 plus O EIA	1	
43	Murex® HIV-1.2.O. Diasorin	2	1
12	Other	4	1
	Total	18	3

*Four 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 31743				
		31741	31742	31743	31744	31745
Avioq HIV-1 Microelisa System (N=8)	Mean	0.09	0.12	2.19	0.10	0.11
	SD	0.01	0.03	0.59	0.02	0.02
	%CV	13.9	26.5	26.9	23.5	18.8

♦ Confirmatory Data

Fifteen 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)	2
36	New LAV Blot I (Bio-Rad)	2
37	Genelab Diagnostics HIV Blot Kit	1
	Total	15

Table 5. Frequency of 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 31743	Positive	14	5	2	10	5	8	0	14	13
	Weak Positive	0	4	4	2	8	0	2	0	1
	Negative	1	6	8	3	2	7	12	1	1
	Indeterminate	0	0	1	0	0	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 (23 Laboratories)

Specimen Number	Expected Value	Non-reactive	Reactive
31741	Non-reactive	23	0
31742	Non-reactive	23	0
31743	Reactive	0	23
31744	Non-reactive	23	0
31745	Non-reactive	23	0

Evaluations

Overall, participants reported no 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 October 2, 2017.

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

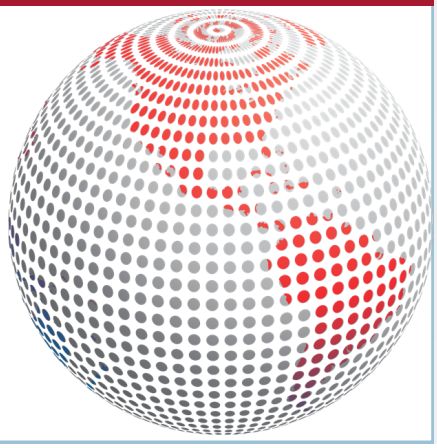
This program is co-sponsored by the Centers for Disease Control and Prevention (CDC) and The Association of Public Health Laboratories (APHL)

NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

Direct inquiries to:

Centers for Disease Control and Prevention
4770 Buford Highway NE, MS/F19
Atlanta, GA 30341-3724
Phone: 404-488-7945 Email: jvm0@cdc.gov

Editors
Joanne Mei
Irene Williams



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INQUIRIES TO:

Irene Williams, Editor • Centers for Disease Control and Prevention (CDC) • Newborn Screening Quality Assurance Program
Mailstop F-24 • 4770 Buford Highway, N.E. • Atlanta, GA 30341-3724
Phone (770) 488-4582 • NSQAPDMT@cdc.gov
E-mail: IWilliams1@cdc.gov