

Newborn Screening Quality Assurance Program

PROFICIENCY TESTING PROGRAM FOR ANTI-HIV-1 IN DRIED BLOOD SPOTS

Quarterly Report

Quarter 3

August 2016

INTRODUCTION

The anti-HIV-1 Antibodies Proficiency Testing (PT) panel for Quarter 3, 2016, consisted of five individual matrix dried blood spot (DBS) specimens representing a variety of serostatuses. Anti-HIV-1 Antibody screening and confirmatory tests should identify all HIV-positive specimens, regardless of subtype. Method and laboratory performance are evaluated by challenging participants with specimens representing HIV-negative and positive serostatuses.

On July 12, 2016, we sent the Quarter 3 anti-HIV-1 Antibodies PT panel to 15 domestic and 13 international participants. We received data reports from 23 of the 28 participating laboratories by the designated deadline date. This report is the outcome of data reported for Quarter 3, 2016 anti-HIV-1 Antibodies PT specimens, and is distributed to all participants and to program colleagues upon request.

Each participant was asked to analyze the specimens for anti-HIV-1 Antibodies with the assay schemes they routinely use and to report for each specimen the screening results along with results from any confir-

matory assays performed for presumptive positives. A final interpretation for each specimen must be submitted to receive an evaluation.

No false negative and no false positive misclassifications were reported.

PARTICIPANTS' RESULTS

Table 1 shows the overall frequency of reported reactive, non-reactive, and indeterminate screening results for specimens 31641- 31645.

In Part 1 of the report (Screening 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 $N \geq 3$.

In Part 2 of the report (Confirmatory testing), Table 4 shows the number of laboratories using each confirmatory method/ kit. Table 5 shows the Reported Frequency of Bands by Western Blot for each of the PT specimens that tested positive for the anti-HIV-1 Antibodies screening analysis.

The Quality Assurance Program will ship next quarter's anti-HIV-1 Antibodies PT in DBS specimens in January 2017. ❖

CONFERENCES AND MEETINGS

American Public Health Association (APHA) Annual Meeting & Exposition, October 29 – November 2, 2016, Denver, CO.



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Quarterly publications for colleagues and participants of the Proficiency Testing Program for Anti-HIV-1 in Dried Blood Spots.

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TABLE 1: Frequency Distribution: Outcome of Final Interpretations (23 Laboratories)

Specimen Number	Expected Value	Non-Reactive	Reactive
31641	Non-Reactive	23	0
31642	Non-Reactive	23	0
31643	Non-Reactive	23	0
31644	Non-Reactive	23	0
31645	Reactive	0	23

Part 1. SCREENING

TABLE 2: Number of EIA Screening Methods Reported; Includes Primary and Secondary Methods

Method Code	Kit Source	Primary	Secondary
11	In House	1	
12	Other	3	
27	Tecnosuma (Cuba) UMELISA HIV 1+2	2	
40	Avioq HIV-1 Microeleisa Systems	12	9
41	Bio-Rad HIV-1/HIV-2 plus O EIA	1	
43	Murex® HIV-1.2.O. Diasorin	<u>1</u>	2
Total Number of Participants:		20*	

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

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TABLE 3: Overall statistics from the EIA method screening assay (N ≥ 3)

METHOD	STATISTIC	SPECIMEN				
		31641	31642	31643	31644	31645
Avioq HIV-1 Microelisa System (N= 12)	MEAN	0.106	0.128	0.112	0.116	2.655
	SD	0.016	0.028	0.032	0.021	0.314
	%CV	15.4	21.6	28.2	18.3	11.8

PART 2. CONFIRMATORY

TABLE 4: Number of Confirmatory Methods Reported

<u>Method Code</u>	<u>Kit Source</u>	<u>Total Participant</u>
16	Genetic Systems HIV-1 WB Kit (Bio-Rad)	11
32	Cambridge Biotech HIV-1 WB Kit (Maxim)	2
35	OraSure HIV-1 WB Kit	1
36	New LAV Blot I (Bio-Rad)	1
37	Genelab Diagnostics HIV 2.2 WB	1
	Total:	<u>16</u>

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TABLE 5: Reported Frequency of Bands for Reactive Specimens (All Methods)

Total # Labs (16)		gp160	gp120	p66	p55	p51	gp41	p31	p24	p18
Interpretation		Number of Laboratories Finding Reactive Bands								
Specimen 31645(R)	Positive	15	16	16	10	14	16	16	15	2
	Weak Positive	1	0	0	5	2	0	0	1	4
	Negative	0	0	0	1	0	0	0	0	9
	Indeterminate	0	0	0	0	0	0	0	0	1

This *NEWBORN SCREENING QUALITY ASSURANCE PROGRAM* report is an internal publication distributed to program participants and selected program colleagues. The laboratory quality assurance program is a project cosponsored by the Centers for Disease Control and Prevention (CDC) and the Association of Public Health Laboratories.

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