

Newborn Screening Quality Assurance Program

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

Quarterly Report

Quarter 4

November 2015

INTRODUCTION

The Anti-HIV-1 proficiency testing (PT) panel for Quarter 4, 2015, consisted of five individual matrix dried blood spot (DBS) specimens representing a variety of serostatuses. HIV 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 October 5, 2015, we sent the Quarter 4 Anti-HIV-1 panel to 14 domestic and 11 international participants. We received data reports from 24 of the 26 participating laboratories by the designated deadline date. This report is the outcome of data reported for Quarter 4, 2015 Anti-HIV-1 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 confirmatory assays performed for presump-

tive 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 41541- 41545.

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.

Tables 3-4 provide the overall statistics for the screening EIA methods where $N \geq 3$.

In Part 2 of the report (Confirmatory testing), Table 5 shows the number of laboratories using each confirmatory method/kit.

Table 6 shows the Reported Frequency of Bands by Western Blot for each of the PT specimens that tested positive for the Anti-HIV-1 screening analysis.

The Quality Assurance Program will ship next quarter's HIV-1 DBS proficiency testing specimens in January 2016. ❖

CONFERENCES AND MEETINGS

3rd International Conference on HIV/AIDS, STDs and STIs- November 30 - December 02, 2015. Hilton Atlanta Airport, Atlanta, USA

National HIV Prevention Conference – December 6-9, 2015. Hyatt Regency Hotel, Atlanta, GA.

2016 HIV Diagnostics Conference -March 21-24, 2016. Hyatt Regency Hotel, Atlanta, GA.
<http://hivtestingconference.org/>



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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 (21 Laboratories)

Specimen Number	Expected Results	Non- Reactive	Reactive	Indeterminate
41541	Non-Reactive	24	0	0
41542	Non-Reactive	23	0	1
41543	Reactive	0	24	0
41544	Reactive	0	24	0
41545	Non-Reactive	23	0	1

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	1	2
27	Tecnosuma (Cuba) UMELISA HIV 1+2	3	
40	Avioq HIV-1 Microelisa Systems	11	5
41	Bio-Rad HIV-1/HIV-2 plus O EIA	1	
43	Murex® HIV-1.2.O. Diasorin	4	1
Total Number of Participants:		21*	

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

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

METHOD	STATISTIC	SPECIMEN				
		41541	41542	41543	41544	41545
Avioq HIV-1 Microelisa System (N=11)	MEAN	0.093	0.103	1.721	1.891	0.108
	SD	0.018	0.021	0.214	0.369	0.019
	%CV	19.5	20.2	12.4	19.5	17.2

TABLE 4: Overall statistics from the EIA method screening assay (N ≥ 3)

METHOD	STATISTIC	SPECIMEN				
		41541	41542	41543	41544	41545
Murex® HIV-1.2.O. Diasorin (N=4)	MEAN	0.195	0.167	6.050	5.821	0.329
	SD	0.0160	0.080	3.272	3.541	0.413
	%CV	82.0	47.9	54.1	60.8	125.3

PART 2. CONFIRMATORY**TABLE 5: Number of Confirmatory Methods Reported**

Method Code	Kit Source	Total Participants
12	Other	0
16	Genetic Systems HIV-1 WB Kit (Bio-Rad)	10
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
42	MP Diagnostics HIV Blot 2.2	1
	Total:	16

TABLE 6: Reported Frequency of Bands for Reactive Specimens (All Methods)

Total # Labs (16)	gp160	gp120	p66	p55	p51	gp41	p31	p24	p18	
Specimen 31543 (R)	Positive	16	10	3	7	6	4	0	15	12
	Weak Positive	0	3	2	3	2	9	3	1	2
	Negative	0	2	9	5	6	1	9	0	0
	Indeterminate	0	1	1	0	1	2	2	0	1
Specimen 31544 (R)	Positive	15	10	7	10	6	6	10	15	1
	Weak Positive	1	3	5	1	3	7	2	1	5
	Negative	0	2	2	4	4	1	3	0	6
	Indeterminate	0	1	1	0	1	1	0	0	3

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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