

Newborn Screening Quality Assurance Program

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

Quarterly Report

Quarter 1

February 2016

INTRODUCTION

The Anti-HIV-1 proficiency testing (PT) panel for Quarter 1, 2016, 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 January 11, 2016, we sent the Quarter 1 Anti-HIV-1 panel to 15 domestic and 12 international participants. We received data reports from 23 of the 27 participating laboratories by the designated deadline date. This report is the outcome of data reported for Quarter 1, 2016 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 11641-11645.

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 $N > 3$.

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 profi-

ciency testing specimens by April 11, 2016. ❖

CONFERENCES AND MEETINGS

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

AIDS 2016 – 21st International AIDS Conference. July 17-22, 2016, Durban, South Africa.



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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 Results	Non- Reactive	Reactive	Indeterminate
11641	Non-Reactive	23	0	0
11642	Non-Reactive	22	0	1
11643	Non-Reactive	23	0	0
11644	Reactive	0	23	0
11645	Reactive	0	23	0

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	2	1
27	Tecnosuma (Cuba) UMELISA HIV 1+2	3	
40	Avioq HIV-1 Microeleisa Systems	11	7
41	Bio-Rad HIV-1/HIV-2 plus O EIA	1	
43	Murex® HIV-1.2.O. Diasorin	<u>3</u>	2
Total Number of Participants:		21*	

*Note: Two 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				
		11641	11642	11643	11644	11645
Avioq HIV-1 Microelisa System (N=11)	MEAN	0.099	0.102	0.114	1.557	1.854
	SD	0.018	0.016	0.026	0.268	0.402
	%CV	17.7	16.1	22.7	17.2	21.7

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

METHOD	STATISTIC	SPECIMEN				
		11641	11642	11643	11644	11645
Murex® HIV-1.2.O. Diasorin (N=3)	MEAN	0.361	0.776	0.462	8.078	8.920
	SD	0.411	0.756	0.573	3.259	4.371
	%CV	113.9	97.5	123.9	40.3	49.0

PART 2. CONFIRMATORY

TABLE 5: Number of Confirmatory Methods Reported

Method Code	Kit Source	Total Participant
16	Genetic Systems HIV-1 WB Kit (Bio-Rad)	9
32	Cambridge Biotech HIV-1 WB Kit (Maxim)	3
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

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TABLE 6: 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 11644 (R)	Positive	16	8	4	8	8	7	1	16	14
	Weak Positive	0	4	4	1	2	4	1	0	1
	Negative	0	3	8	6	6	3	12	0	0
	Indeterminate	0	1	0	0	0	2	2	0	1
Specimen 11645 (R)	Positive	16	10	14	11	11	11	11	16	5
	Weak Positive	0	2	1	0	2	3	1	0	3
	Negative	0	2	0	4	2	2	3	0	5
	Indeterminate	0	2	1	1	1	0	1	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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