

Newborn Screening Quality Assurance Program

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

Quarterly Report

Quarter 4

December 2014

INTRODUCTION

The Anti-HIV-1 proficiency testing (PT) panel for Quarter 4, 2014, 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 14, 2014, we sent the Quarter 4 Anti-HIV-1 panel to 17 domestic and 11 international participants. We received data reports from 25 of the 28 participating laboratories by the designated deadline date. This report is the outcome of data reported for Quarter 4, 2014, 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 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 presumptive positives. A final interpretation for each specimen must be submitted to receive an evaluation.

There were no false negative and no false positive assessments reported.

PARTICIPANTS' RESULTS

Table 1 shows the overall frequency of reported reactive, non-reactive, and indeterminate screening results for specimens 41441- 41445.

In Part 1 of the report, 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 $N > 3$.

In Part 2 of the report, 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 screening analysis.

The Quality Assurance Program will ship next quarter's HIV-1 DBS proficiency testing specimens on January 12, 2015. ❖

CONFERENCES AND MEETINGS

Keynote Symposia: Mechanisms of HIV Persistence: Implications for a Cure. April 26 - May 1, 2015 Boston, MA, USA

8TH IAS Conference on HIV Pathogenesis, Treatment and Prevention. July 19-22, 2015 Vancouver, British Columbia, Canada



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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 (25 Laboratories)

Specimen Number	Expected Results	Non- Reactive	Reactive	Indeterminate
41441	Non-Reactive	25	0	0
41442	Non-Reactive	25	0	0
41443	Non-Reactive	25	0	0
41444	Reactive	0	25	0
41445	Reactive	0	25	0

Part 1. SCREENING

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

<u>Method Code</u>	<u>Kit Source</u>	<u>Participants</u>
11	In House	1
12	Other	3
27	Tecnosuma (Cuba) UMELISA HIV 1+2	2
40	Avioq HIV-1 Microeleisa Systems	13
41	Bio-Rad HIV-1/HIV-2 plus O EIA	1
43	Murex® HIV-1.2.O. Diasorin	1
	Total	21*

*Note: Four 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				
		41441	41442	41443	41444	41445
Avioq HIV-1 Microelisa System (N=13)	OUTLIERS	1	0	0	0	0
	MEAN	0.102	0.090	0.110	1.821	2.043
	SD	0.016	0.018	0.019	0.385	0.446
	UL 95%	0.135	0.126	0.147	2.576	2.917
	LL 95%	0.070	0.055	0.073	1.066	1.169

PART 2. CONFIRMATORY

TABLE 4: Number of Confirmatory Methods Reported

Method Code	Kit Source	Total Participants
12	DAVIH Blot	1
16	Genetic Systems HIV-1 WB Kit (Bio-Rad)	13
32	Cambridge Biotech HIV-1 WB Kit (Maxim)	2
36	New LAV Blot I (Bio-Rad)	1
37	Genelab Diagnostics HIV 2.2 WB	1
	Total:	18

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

Total # Labs (18)	gp160	gp120	p66	p55	p51	gp41	p31	p24	p18
	Number of Laboratories Finding Reactive Bands								
Specimen 41444 (R)	17	14	7	12	10	15	3	18	15
Specimen 41445 (R)	18	16	13	14	9	15	10	18	8

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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