

Newborn Screening Quality Assurance Program

PROFICIENCY TESTING PROGRAM FOR ANTI HIV 1 IN DRIED BLOOD

Quarterly Report

Quarter 3

August 2014

INTRODUCTION

The Anti-HIV-1 proficiency testing (PT) panel for Quarter 3, 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 July 15, 2014, we sent the Quarter 3 Anti-HIV-1 panel to 17 domestic and 13 international participants. We received data reports from 27 of the 30 participating laboratories by the designated deadline date. This report is the outcome of data reported for the Quarter 3, 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 a grade.

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 31441-31445.

In Part 1 of the report, Table 2 shows the number of laboratories using EIA screening methods/kits both for the primary and secondary screens.

Table 3 provides the overall statistics from the enzyme immunoassay methods screening assay where $N \geq 3$.

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 October 14, 2014. ❖

CONFERENCES AND MEETINGS

16th Annual International Meeting of the Institute of Human Virology
September 14 - 17, 2014
Baltimore Sheraton Inner Harbor, Baltimore, MD.

U.S. Conference on AIDS
October 2 - October 5, 2014
Hilton San Diego Bayfront Hotel, San Diego, CA.



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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 (27 Laboratories)

Specimen Number	Expected Results	Non- Reactive	Reactive	Indeterminate
31441	Non-Reactive	27	0	0
31442	Non-Reactive	27	0	0
31443	Reactive	0	27	0
31444	Reactive	0	27	0
31445	Non-Reactive	27	0	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	4
12	Other (Murex 1.2.0)	3
27	Tecnosuma (Cuba) UMELISA HIV 1+2	2
40	Avioq HIV-1 Microeleisa Systems	12
41	Bio-Rad HIV-1/HIV-2 plus O EIA	1
	Total	27*

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

TABLE 3: Overall statistics from the EIA methods screening assay (N_≥3)

METHOD	STATISTIC	SPECIMEN				
		31441	31442	31443	31444	31445
Avioq HIV-1 Microelisa System (N=12)	OUTLIERS	1	0	0	0	0
	MEAN	0.103	0.104	2.998	1.896	0.124
	SD	0.01	0.02	0.18	0.23	0.02
	UL 95%	0.120	0.135	3.355	2.353	0.167
	LL 95%	0.087	0.073	2.641	1.440	0.081
Murex HIV 1.2.0 EIA (N=3)	OUTLIERS	0	0	0	0	0
	MEAN	0.176	0.149	5.911	5.649	0.205
	SD	0.12	0.10	3.54	3.79	0.04
	UL 95%	0.412	0.336	12.850	13.070	0.279
	LL 95%	0.000	0.000	0.000	0.000	0.131

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)	2
37	Genelab Diagnostics HIV 2.2 WB	1
Total:		19

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

Total # Labs (19)	gp160	gp120	p66	p55	p51	gp41	p31	p24	p18
	Number of Laboratories Finding Reactive Bands								
Specimen 31443 (R)	19	19	19	18	16	19	18	18	6
Specimen 31444 (R)	19	18	18	13	11	15	15	19	9

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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