

Newborn Screening Quality Assurance Program

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

Quarterly Report

Quarter 1

February 2014

INTRODUCTION

The Anti-HIV-1 proficiency testing (PT) panel for Quarter 1, 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 January 14, 2014, we sent the Quarter 4 Anti-HIV-1 panel to 18 domestic and 13 international participants. We received data reports from 29 of the 31 participating laboratories by the designated deadline date. This report is the outcome of data reported for the Quarter 1, 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 11441-11445.

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 April 14, 2014. ❖

CONFERENCES AND MEETINGS

2nd International Science Symposium on HIV & Infectious Diseases (HIV SCIENCE 2014) - To be held at the ACCORD Metropolitan Hotel, T Nagar, Chennai, India. Please visit the symposium website at <http://HIVSCIENCE.yrgcare.org> to learn more about the event

The 30th Annual Clinical Virology Symposium and Annual Meeting of the Pan American Society for Clinical Virology will be held April 27 - 30, 2014 at the Hilton Daytona Beach Oceanfront Resort, Daytona Beach, FL. For information visit <http://www.clinicalvirologysymposium.org/>



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Anti-HIV-1 PT Report

Quarter 1, 2014

TABLE 1: Frequency Distribution: Outcome of Final Interpretations (29 Laboratories)

Specimen Number	Expected Results	Non- Reactive	Reactive	Indeterminate
11441	Non-Reactive	29	0	0
11442	Reactive	0	29	0
11443	Non-Reactive	26	0	3
11444	Non-Reactive	28	0	1
11445	Non-Reactive	29	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	5
12	Other (Murex 1.2.0)	3
27	Tecnosuma (Cuba) UMELISA HIV 1+2	3
40	Avioq HIV-1 Microeleisa Systems	16
41	Bio-Rad HIV-1/HIV-2 plus O EIA	1
	Total	29*

*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				
		11441	11442	11443	11444	11445
Avioq HIV-1 Microelisa System (N=16)	OUTLIERS	0	0	0	0	0
	MEAN	0.111	1.949	0.104	0.095	0.096
	SD	0.029	0.323	0.024	0.024	0.027
	UL 95%	0.168	2.582	0.151	0.143	0.149
	LL 95%	0.053	1.316	0.056	0.048	0.042
Tecnosuma UMELISA HIV 1+2 (N=3)	OUTLIERS	1	1	1	1	1
	MEAN	0.345	1.323	0.297	0.229	0.218
	SD	0.188	0.132	0.220	0.145	0.088
	UL 95%	0.714	1.582	0.728	0.513	0.391
	LL 95%	0.000	1.063	0.000	0.000	0.044
Murex HIV 1.2.0 EIA (N=3)	OUTLIERS	0	1	1	0	1
	MEAN	0.160	3.120	0.125	0.164	0.119
	SD	0.052	1.009	0.025	0.049	0.029
	UL 95%	0.263	5.097	0.175	0.260	0.175
	LL 95%	0.058	1.142	0.075	0.067	0.062

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)	14
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: 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 11442 (R)	19	15	7	15	11	14	8	19	17

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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