

Newborn Screening Quality Assurance Program

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

Quarterly Report

Quarter 3

August 2013

INTRODUCTION

The Anti-HIV-1 proficiency testing (PT) panel for Quarter 3, 2013, 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, 2013, we sent the Quarter 3 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 3, 2013, Anti-HIV-1 PT specimens. This quarterly report 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 results reported. Four indeterminate results from Western Blot methods were reported for specimen 31342.

PARTICIPANTS' RESULTS

Table 1 shows the overall frequency of reported reactive, non-reactive, and indeterminate screening results for specimens 31341-31345.

In Part 1 of the report, Table 2 shows the number of laboratories using each screening method/kit both for the primary and secondary screens.

Table 3 provides the overall statistics from the enzyme immunoassay methods screening assays 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 15, 2013. ❖

CONFERENCES AND MEETINGS

American Public Health Association (APHA) - 141st Annual Meeting and Exposition
Dates: November 2-6, 2013
City: Boston, MA
Country: United States

6th International HIV Persistence Workshop
Dates: December 3-6, 2013
City: Miami, FL
Country: United States



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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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**Anti-HIV-1 PT Report
Quarter 3, 2013**

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

Specimen Number	Expected Results	Non- Reactive	Reactive	Indeterminate	Not Reported
31341	Non-Reactive	29	0	0	0
31342	Non-Reactive	25	0	4	0
31343	Non-Reactive	29	0	0	0
31344	Non-Reactive	29	0	0	0
31345	Reactive	0	29	0	0

Part 1. SCREENING

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

Method Code	Kit Source	Participants
10	Fujirebio Serodia-HIV 1,2	1
11	In House	1
12	(Other) Murex HIV 1.2.0 EIA	3
12	(Other) NeoMAP Doenças Infecciosas IgG	2
12	(Other) Siemans Centaur cHIV	1
27	Tecnosuma (Cuba) UMELISA HIV 1+2	3
40	Avioq HIV-1 Microeleisa Systems	13
41	Bio-Rad HIV-1/HIV-2 plus O EIA	1
		25*

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

TABLE 3: SCREENING STATISTICS BY METHOD

SPECIMEN ID	Avioq HIV-1 Microelisa System (N=13)					Tecnosuma UMELISA HIV 1+2 (N=3)					Murex HIV 1.2.0 EIA (N=3)				
	OUTLIERS	MEAN	SD	UL 95%	LL 95%	OUTLIERS*	MEAN	SD	UL 95%	LL 95%	OUTLIERS*	MEAN	SD	UL 95%	LL 95%
31341	0	0.099	0.023	0.144	0.053	1	0.108	0.021	0.148	0.067	1	0.073	0.001	0.074	0.071
31342	0	0.115	0.036	0.186	0.044	1	0.153	0.061	0.272	0.034	1	0.084	0.004	0.090	0.077
31343	0	0.126	0.042	0.207	0.044	1	0.251	0.047	0.342	0.160	1	0.162	0.095	0.349	0.000
31344	0	0.109	0.032	0.172	0.046	1	0.216	0.008	0.233	0.199	1	0.077	0.009	0.094	0.060
31345	0	1.662	0.429	2.503	0.821	1	0.936	0.164	1.258	0.614	1	3.754	0.221	4.186	3.322

*Outlier data not included in calculations

PART 2. CONFIRMATORY**TABLE 4: Number of Confirmatory Methods Reported**

Method Code	Kit Source	Total Participants
16	Genetic Systems HIV-1 WB Kit (Bio-Rad)	13
32	Cambridge Biotech HIV-1 WB Kit (Maxim)	2
12	Other: NeoMAP, Brazil	1
35	Ora-Sure HIV-1 WB Kit	1
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 31345 (R)	19	17	8	12	16	16	6	18	19

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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