

Newborn Screening Quality Assurance Program

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

Quarterly Report

Quarter 2

May 2013

INTRODUCTION

The Anti-HIV-1 proficiency testing (PT) panel for Quarter 2, 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 April 8, 2013, we sent the Quarter 2 Anti-HIV-1 panel to 18 domestic and 13 international participants. We received data reports from 28 of the 31 participating laboratories by the designated deadline date. This report is the outcome of data reported for the Quarter 2, 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 an evaluation.

There were no false negative and no false positive results reported. Two and three indeterminate results from Western Blot methods were reported for specimens 21341 and 21342, respectively.

PARTICIPANTS' RESULTS

Table 1 shows the overall frequency of reported reactive, non-reactive, and indeterminate screening results for specimens 21341-21345.

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 shows the summary of screening and confirmatory errors by method.

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 July 15, 2013. ❖

CONFERENCES AND MEETINGS

7th IAS Conference on HIV Pathogenesis, Treatment and Prevention 2013

Dates: 06/30/2013- 07/03/2013

City: Kuala Lumpur

Country: Malaysia

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 2, 2013**

TABLE 1: Frequency Distribution: Outcome of Final Interpretations (28 Labs)

Specimen Number	Expected Results	Non- Reactive	Reactive	Indeterminate	Not Reported
21341	Non-Reactive	26	0	2	3
21342	Non-Reactive	25	0	3	3
21343	Non-Reactive	28	0	0	3
21344	Reactive	0	28	0	3
21345	Reactive	0	28	0	3

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	2
11	In House	1
12	Other	4
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
Total		24*

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

TABLE 3: Summary of screening and confirmatory errors by method

	21341		21342		21343		21344		21345	
	FP	IND	FP	IND	FP	IND	FN	IND	FN	IND
All Anti-HIV-1 EIA Methods										
10	Fujirebio Serodia-HIV 1,2 (FDA Licensed for DBS)	0	0	0	0	0	0	0	0	0
27	Tecnosuma (Cuba) UMELISA HIV 1+2	0	0	0	0	0	0	0	0	0
34	Q-Preven HIV 1+2, DBS, Brazil	0	0	0	0	0	0	0	0	0
40	Avioq HIV-1 Microeleisa Systems	0	0	0	0	0	0	0	0	0
41	Bio-Rad HIV-1/HIV-2 plus O EIA	0	0	0	0	0	0	0	0	0
11	In House	0	0	0	0	0	0	0	0	0
12	Other	0	0	0	0	0	0	0	0	0
All Anti-HIV-1 Confirmatory Methods										
16	Genetic Systems HIV-1 WB (Bio-Rad) (FDA Licensed for DBS)	0	2	0	3	0	0	0	0	0
32	Cambridge Biotech HIV-1 WB Kit (Maxim)	0	0	0	0	0	0	0	0	0
35	OraSure HIV-1 WB Kit	0	0	0	0	0	0	0	0	0
36	New LAV Blot I (Bio-Rad)	0	0	0	0	0	0	0	0	0
37	Genelab Diagnostics HIV Blot Kit	0	0	0	0	0	0	0	0	0
42	MP Diagnostics HIV Blot 2.2	0	0	0	0	0	0	0	0	0
11	In House	0	0	0	0	0	0	0	0	0
12	Other	0	0	0	0	0	0	0	0	0

PART 2. CONFIRMATORY

TABLE 4: Number of Confirmatory Methods Reported

<u>Method Code</u>	<u>Kit Source</u>	<u>Total Participants</u>
16	Genetic Systems HIV-1 WB Kit (Bio-Rad)	14
32	Cambridge Biotech HIV-1 WB Kit (Maxim)	2
12	Other: NeoMAP, Brazil	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 20

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

Total # Labs (18)	gp160	gp120	p66	p55	p51	gp41	p31	p24	p18
Specimen 21344 (R)	20	19	9	16	13	14	6	20	20
Specimen 21345 (R)	20	19	17	17	17	18	17	20	13

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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