



Newborn Screening Quality Assurance Program

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

Quarterly Report

Quarter 2

May 2012

INTRODUCTION

The Anti-HIV-1 proficiency testing (PT) panel for Quarter 2, 2012, 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 9, 2012, we sent the Quarter 2 Anti-HIV-1 panel to 27 total participants. We received data reports from 26 participating laboratories by the designated deadline date. This report is the outcome of data reported for the Quarter 2, 2012, 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 using 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.

PARTICIPANTS' RESULTS

Table 1 shows the overall frequency of reported reactive, non-reactive, and indeterminate screening results for specimens 21241-21245.

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 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 16, 2012 and the next major allotment of HIV-1 DBS quality control specimens on July 16, 2012.

CONFERENCES AND MEETINGS

- Congress on HIV and Emerging Infectious Diseases, Marseille, France, May 23-25, 2012.
- 19th International AIDS Conference, Washington D.C., July 22, 2012.

SPOTLIGHT

May 18, 2012 was HIV Vaccine Awareness Day, which is an annual observance to raise awareness of the importance of preventive HIV vaccine research.



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**Anti-HIV-1 PT Report
Quarter 2, 2012**

TABLE 1: Frequency Distribution: Outcome of Final Interpretations (27 Labs)

Specimen Number	Expected Results	Non- Reactive	Reactive	Indeterminate	Not Reported
21241	Non-Reactive	25	0	1	1
21242	Non-Reactive	26	0	0	1
21243	Reactive	0	26	0	1
21244	Reactive	0	26	0	1
21245	Non-Reactive	26	0	0	1

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	6
27	Tecnosuma (Cuba) UMELISA HIV 1+2	3
40	Avioq HIV-1 Microeleisa Systems	11
41	Bio-Rad HIV-1/Hiv-2 plus O EIA	2
	Total	25*

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

TABLE 3: : Summary of screening errors by method.

All Methods	21241		21242		21243		21244		21245	
	FP	IND	FP	IND	FN	IND	FN	IND	FP	IND
10 Fujirebio Serodia-HIV 1,2										
15 Genetic Systems rLAV EIA (Bio-Rad)										
27 Tecnosuma (Cuba) UMELISA HIV 1+2										
34 Q-Preven HIV 1+2, DBS, Brazil										
40 Avioq HIV-1 Microeleisa Systems										
41 Bio-Rad HIV-1/HIV-2 plus O EIA										
11 In House										
12 Other				1						
16 Genetic systems HIV-1 WB Kit (Bio-Rad)										

False Pos = 0

False Neg = 0

Indeterminant = 1

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)	12
32	Cambridge Biotech HIV-1 WB Kit (Maxim)	2
35	OraSure HIV-1 WB Kit	1
36	Bio-Rad New LAV Blot I	1
37	Genelab Diagnostics HIV 2.2 WB	1
42	MP Diagnostics HIV Blot 2.2	1

		Total 18

Tables 5: Reported Frequency of Bands for Reactive (R) Specimens 21243 and 21244 (All methods)

Total # Labs (18)	gp160	gp120	p66	p55	p51	gp41	p31	p24	p18
Number of Laboratories Finding Reactive Bands									
Specimen 21243 (R)	18	15	8	13	13	16	5	18	17
Specimen 21244 (R)	18	15	17	13	14	16	17	18	11

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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