



Newborn Screening Quality Assurance Program

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

Quarterly Report

Quarter 2

May 2010

INTRODUCTION

The Anti-HIV-1 proficiency testing (PT) panel for Quarter 2, 2010 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 12, 2010, we sent the Quarter 2 Anti-HIV-1 panel to 79 total participants. We received data reports from 75 participating laboratories by the designated deadline date. This report is the outcome of data reported for the Quarter 2, 2010 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 2041-2045.

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. There were five false negative and six indeterminate results for specimen 2045. This specimen was the weakly reactive QC material Lot # 74.

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 and the next major allotment of HIV-1 DBS quality control specimens on July 19, 2010. ❖

Future Meetings:

XVIII International AIDS Conference
Vienna, Austria
July 18-23, 2010

AIDS 2010
Atlanta, Georgia
Sept. 28 to Oct. 1, 2010

SPOTLIGHT

The Center for AIDS Research at Emory University (CFAR) will serve as Local Host of AIDS Vaccine 2010, the largest and most important global scientific conference focused on AIDS vaccine research. This conference helps to cultivate a global network of scientific talent to carry the field of HIV vaccine research into the future. AIDS Vaccine 2010 will welcome a large cohort of promising early career scientists both nationally and internationally through conference scholarships and travel support.



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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 (#Labs)

Specimen Number	Expected Results	Reactive	Non-reactive	Indeterminate	Not Reported
2041	Reactive	75	0	0	4
2042	Non-Reactive	2	71	2	4
2043	Reactive	75	0	0	4
2044	Non-Reactive	1	74	0	4
2045	Reactive	64	5	6	4

Part 1. SCREENING

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

<u>Method Code</u>	<u>Kit Source</u>	<u>Participants</u>
10	Fujirebio Serodia-HIV 1,2	2
11	In House	1
12	Other (Please specify in detail)	7
15	rLAV EIA (Bio-Rad)	10
20	bioMerieux Vironostika UniForm II Ag/AB	4
21	bioMerieux Vironostika Uni-Form II plus O	5
22	Genescreen HIV 1/2 V2	2
23	Genescreen Plus HIV Ag/Ab (BioRad)	1
24	Murex HIV 1.2.0 (Abbott)	22
25	Murex HIV Ag/Ab Combination (Abbott)	1
26	Recombinant HIV 1/2, Russia	6
27	Tecnosuma (Cuba) UMELISA HIV 1+2	3
28	CombiBest Anti-HIV 1, 2 DCM, Russia	0
29	CombiBest 1/2, Ag/Ab, Russia	0
30	Anti-HIV Unif, Russia	15
31	Dade Behring Enzygnost Anti-HIV 1/2 Plus O	0
33	UniBest HIV 1,2 AB, Russia	8
34	Q-Preven HIV 1+2, DBS, Brazil	1
39	Genescreen Ultra HIV AG-AB	16
40	Avioq HIV-1 Microeleisa Systems	12
41	Bio-Rad HIV-1/Hiv-2 plus O EIA	2
<hr/>		Total 108

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TABLE 3. Quarter 2, 2010, Summary of Errors by Screening Method

Method Code	Kit Source	2041		2042		2043		2044		2045	
		FN	I	FP	I	FN	I	FP	I	FN	I
10	Fujirebio Serodia-HIV 1,2										
15	Genetic Systems rLAV EIA (Bio-Rad)									2	2
20	bioMerieux Vironostika Uni-Form II Ag/AB									1	
21	bioMerieux Vironostika Uni-Form II plus O										1
22	Genescreen HIV 1,2 V2										
23	Genescreen Plus HIV Ag/Ab (BioRad)										
39	Genescreen Ultra HIV Ag/Ab (BioRad)										
24	Murex HIV 1.2.0 (Abbott)										3
26	Recombinant HIV 1/2, Russia										
27	Tecnosuma (Cuba) UMELISA HIV 1+2				1					1	
28	CombiBest Anti-HIV 1, 2 DCM, Russia										
29	CombiBest 1/2, Ag/Ab, Russia										
30	Anti-HIV Unif, Russia			2	1	1				1	
31	Dade Behring Enzygnost Anti-HIV 1/2 Plus O										
33	UniBest HIV 1,2 AB, Russia										
40	Avioq HIV-1 Microelisa Systems										
41	Bio-Rad HIV-1/HIV-2 plus O EIA										
11	In House										
12	Other										
	Total: False negative results = 6					1				5	
	False positive results = 2			2							
	Indeterminate = 8				2						6

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)	12
32	Cambridge Biotech HIV-1 WB Kit (Maxim)	4
35	OraSure HIV-1 WB Kit	1
36	Bio-Rad New LAV Blot I	5
37	Genelab Diagnostics HIV 2.2 WB	2
42	MP Diagnostics HIV Blot 2.2	2
12	Other (INNO-LIA HIV ½)	1
		<hr/> Total 27

**Tables 5: Reported Frequency of Bands for Reactive Specimens 2041, and 2043 and 2045
(All methods included)**

Total # Labs (27)	160	120	66	55	51	41	31	24	18
	Number of Laboratories Finding Reactive Bands								
Specimen 2041 (R)	26	27	25	24	25	27	26	26	25
Specimen 2043 (R)	26	19	16	20	14	18	20	26	18
Specimen 2045 (R)	21	12	11	9	7	13	11	20	6

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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