



Newborn Screening Quality Assurance Program

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

Quarterly Report

Quarter 1

February 2010

INTRODUCTION

The Anti-HIV-1 proficiency testing (PT) panel for Quarter 1, 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 January 19, 2010, we sent the Quarter 1 Anti-HIV-1 panel to 80 total participants. We received data reports from 45 participating laboratories by the designated deadline date. This report is the outcome of data reported for the Quarter 1, 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 and non-reactive screening results for specimens 1041-1045.

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 no false negatives errors, 1 false positive error, and 1 indeterminate error for Quarter 1, 2010.

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 April 12, 2010. ❖

Future Meetings:

2010 HIV Diagnostics Conference
Doubletree Hotel Universal

Orlando, FL
March 24-26, 2010

19th Annual HIV Conference
Rosen Shingle Creek,
Orlando, Florida
May 14-15, 2010

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

SPOTLIGHT

The researchers, from Imperial College London and Harvard University, have grown a crystal that reveals the structure of an enzyme called integrase, which is found in retroviruses like HIV. When HIV infects someone, it uses integrase to paste a copy of its genetic information into their DNA. This research shows that retroviral integrase has quite a different structure to that which had been predicted based on earlier research. Availability of the integrase structure means that researchers can begin to fully understand how existing drugs that inhibit integrase are working, how they might be improved, and how to stop HIV developing resistance to them. Posted on: Sunday, 31 January 2010, 13:10 CST
http://www.redorbit.com/news/health/1816233/breakthrough_in_hiv_research/index.html



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Quarter 1, 2010

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

Specimen Number	Expected Results	Reactive	Non-reactive	Indeterminate	Not Reported
1041	Reactive	45	0	0	35
1042	Non-Reactive	0	44	1	35
1043	Non-Reactive	0	45	0	35
1044	Reactive	45	0	0	35
1045	Non-Reactive	1	44	0	35

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	2
12	Other (Please specify in detail)	6
15	Genetic Systems rLAV EIA (Bio-Rad)	9
20	bioMerieux Vironostika UniForm II Ag/AB	3
21	bioMerieux Vironostika Uni-Form II plus O	6
22	Genescreen HIV 1/2 V2	2
23	Genescreen Plus HIV Ag/Ab (BioRad)	1
24	Murex HIV 1.2.0 (Abbott)	4
25	Murex HIV Ag/Ab Combination (Abbott)	0
26	Recombinant HIV 1/2, Russia	2
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	8
31	Dade Behring Enzygnost Anti-HIV 1/2 Plus O	1
33	UniBest HIV 1,2 AB, Russia	0
34	Q-Preven HIV 1+2, DBS, Brazil	1
39	Genescreen Ultra HIV AG-AB	9
40	Avioq HIV-1 Microeleisa Systems	1
41	Bio-Rad HIV-1/Hiv-2 plus O EIA	<u>1</u>
	Total	61

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TABLE 3. Quarter 1, 2010, Summary of Errors by Screening Method

Method Code	Kit Source	1041 (R) FN	1042 (NR) FP	1043 (NR) FP	1044 (R) FN	1045 (NR) FP
10	Fujirebio Serodia-HIV 1,2					
15	Genetic Systems rLAV EIA (Bio-Rad)					
20	bioMerieux Vironostika Uni-Form II Ag/AB					
21	bioMerieux Vironostika Uni-Form II plus O					
22	Genescreen HIV 1,2 V2		(I)			
23	Genescreen Plus HIV Ag/Ab (BioRad)					
39	Genescreen Ultra HIV Ag/Ab (BioRad)					
24	Murex HIV 1.2.0 (Abbott)					
26	Recombinant HIV 1/2, Russia					
27	Tecnosuma (Cuba) UMELISA HIV 1+2					1
28	CombiBest Anti-HIV 1, 2 DCM, Russia					
29	CombiBest 1/2, Ag/Ab, Russia					
30	Anti-HIV Unif, Russia					
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 = 0					
	False positive results = 1					1
	Indeterminate = 1		1			

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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)	11
32	Cambridge Biotech HIV-1 WB Kit (Maxim)	2
35	OraSure HIV-1 WB Kit	0
36	Bio-Rad New LAV Blot I	4
37	Genelab Diagnostics HIV 2.2 WB	2
42	MP Diagnostics HIV Blot 2.2	1
12	Other (INNO-LIA HIV ½)	1
		Total 21

Tables 5: Reported Frequency of Bands for Reactive Specimens 1041, and 1044 (All methods included)

Total # Labs (21)	160	120	66	55	51	41	31	24	18
	Number of Laboratories Finding Reactive Bands								
Specimen 1041 (R)	20	21	19	19	20	21	20	21	20
Specimen 1044 (R)	29	21	19	18	18	20	19	21	12

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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