



Newborn Screening Quality Assurance Program

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

Quarterly Report

Quarter 3

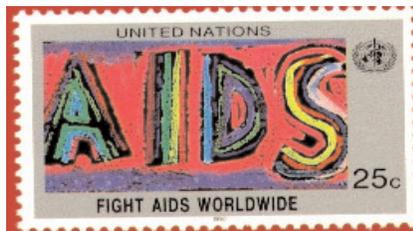
August 2009

INTRODUCTION

The Anti-HIV-1 proficiency testing (PT) panel for Quarter 3, 2009 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 20, 2009, we sent the Quarter 3 Anti-HIV-1 panel to 64 total participants. We received data reports from 55 participating laboratories by the designated deadline date. This report is the outcome of data reported for the Quarter 3, 2009 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 3941-3945.

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 errors for Quarter 3, 2009.

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 October 13, 2009. ❖

Future Meetings:

2010 HIV Diagnostics Conference
Doubletree Hotel Universal
Orlando
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



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Quarterly publications for colleagues and participants of the Proficiency
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TABLE 1: Frequency Distribution: Outcome of Final Interpretations (#Labs)

Specimen Number	Expected Results	Reactive	Non-reactive	Indeterminate	Not Reported
3941	Reactive	55	0	0	8
3942	Reactive	55	0	0	8
3943	Non-Reactive	55	0	0	8
3944	Reactive	54	0	1	8
3945	Non-Reactive	55	0	0	8

Part 1. SCREENING

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

Method Code	Kit Source	Participants
6	bioMerieux Vironostika HIV-1	0
10	Fujirebio Serodia-HIV 1,2	3
11	In House	2
12	Other (Please specify in detail)	9
15	Genetic Systems rLAV EIA (Bio-Rad)	12
20	bioMerieux Vironostika UniForm II Ag/AB	2
21	bioMerieux Vironostika Uni-Form II plus O	5
22	Genescreen HIV 1/2 V2	4
23	Genescreen Plus HIV Ag/Ab (BioRad)	1
24	Murex HIV 1.2.0 (Abbott)	15
25	Murex HIV Ag/Ab Combination (Abbott)	3
26	Recombinant HIV 1/2, Russia	2
27	Tecnosuma (Cuba) UMELISA HIV 1+2	2
28	CombiBest Anti-HIV 1, 2 DCM, Russia	1
29	CombiBest 1/2, Ag/Ab, Russia	1
30	Anti-HIV Unif, Russia	5
31	Dade Behring Enzygnost Anti-HIV 1/2 Plus O	1
33	UniBest HIV 1,2 AB, Russia	10
34	Q-Preven HIV 1+2, DBS, Brazil	1
39	Genescreen Ultra HIV AG-AB	5
Total		84

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TABLE 3. Quarter 3, 2009, Summary of Errors by Screening Method

Method Code	Kit Source	3941 (R)	3942 (R)	3943 (NR)	3944 (R)	3945 (NR)
6	bioMerieux Vironostika HIV-1					
10	Fujirebio Serodia-HIV 1,2					
15	Genetic Systems rLAV EIA (Bio-Rad)					
20	bioMerieux Vironostika UniForm II Ag/AB					
21	bioMerieux Vironostika Uni-Form II plus O					
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)					
26	Recombinant HIV 1/2, Russia					
27	Tecnosuma (Cuba) UMELISA HIV 1+2					
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					
11	In House					
12	Other (Please specify in detail)					
	TOTAL					
	False negative results = 0					

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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 (Bio-Rad)	12
32	Cambridge Biotech HIV-1 WB Kit (Maxim)	3
35	OraSure HIV-1 WB Kit	1
36	Bio-Rad New LAV Blot I	5
37	Genelab Diagnostics HIV 2.2 WB	3
38	ImmunoComb II HIV 1&2 CombFirm (Orgenics)	0
12	Other (MP Diagnostics HIV Blot 2.2)	3
		Total 27

Tables 5: Reported Frequency of Bands for Reactive Specimens 3941, 3942, and 3944 (All methods included)

Total Labs (23)	160	120	66	55	51	41	31	24	18
	Number of Laboratories Finding Reactive Bands								
Specimen 3941 (R)	26	27	21	23	18	27	23	27	20
Specimen 3942 (R)	26	27	24	22	25	27	26	27	26
Specimen 3944 (R)	26	22	11	19	10	21	7	27	24

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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