



# Newborn Screening Quality Assurance Program

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

Quarterly Report

Quarter 2

May 2009

### INTRODUCTION

The Anti-HIV-1 proficiency testing (PT) panel for Quarter 2, 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 April 13, 2009, we sent the Quarter 2 Anti-HIV-1 panel to 64 total participants. We received data reports from 59 participating laboratories by the designated deadline date. This report is the outcome of data reported for the Quarter 2, 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 2941-2945.

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 was one false negative result reported for specimen 2944.

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 20, 2009. ❖

### Future Meetings:

5<sup>th</sup> IAS Conference on HIV Pathogenesis, Treatment and Prevention, July 19-22, 2009, Cape Town, South Africa.

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

### Spotlight

*CELEBRATION OF THE FIRST  
SICKLE CELL DISEASE WORLD  
DAY UN*, New York 19th June  
2009.

Quarterly publications for colleagues and participants of the Proficiency Testing Program for Anti-HIV-1 in Dried Blood Spots.



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## Quarter 2, 2009

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

Specimen Number	Expected Results	Reactive	Non-reactive	Indeterminate	Not Reported
2941	Reactive	59	0	0	5
2942	Reactive	59	0	0	5
2943	Non-Reactive	0	59	0	5
2944	Reactive	57	1	1	5
2945	Non-Reactive	0	59	0	5

### 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	2
11	In House	1
12	Other (Please specify in detail)	5
15	Genetic Systems rLAV EIA (Bio-Rad)	14
20	bioMerieux Vironostika UniForm II Ag/AB	3
21	bioMerieux Vironostika Uni-Form II plus O	6
22	Genescreen HIV 1/2 V2	3
23	Genescreen Plus HIV Ag/Ab (BioRad)	2
24	Murex HIV 1.2.0 (Abbott)	15
25	Murex HIV Ag/Ab Combination (Abbott)	4
26	Recombinant HIV 1/2, Russia	4
27	Tecnosuma (Cuba) UMELISA HIV 1+2	2
28	CombiBest Anti-HIV 1, 2 DCM, Russia	3
29	CombiBest 1/2, Ag/Ab, Russia	2
30	Anti-HIV Unif, Russia	3
31	Dade Behring Enzygnost Anti-HIV 1/2 Plus O	1
33	UniBest HIV 1,2 AB, Russia	8
34	Q-Preven HIV 1+2, DBS, Brazil	1
39	Genescreen Ultra HIV AG-AB	4
	Total	83

## Quarter 2, 2009

**TABLE 3. Quarter 2, 2009, Summary of Errors by Screening Method**

Method Code	Kit Source	2941 (R) FN	2942 (R) FN	2943 (NR) FP	2944 (R) FN	2945 (NR) FP
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)				1	
	<b>TOTAL</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>
	<b>False negative results = 1</b>					

**Quarter 2, 2009**

**PART 2. CONFIRMATORY**

**Table 4: Number of Confirmatory Methods Reported**

<b>Method Code</b>	<b>Kit Source</b>	<b>Total Participants</b>
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 2941, 2942, and 2945 (All methods included)**

<b>Total Labs (23)</b>	<b>160</b>	<b>120</b>	<b>66</b>	<b>55</b>	<b>51</b>	<b>41</b>	<b>31</b>	<b>24</b>	<b>18</b>
	Number of Laboratories Finding Reactive Bands								
<b>Specimen 2941 (R)</b>	26	27	23	18	23	27	27	26	18
<b>Specimen 2942 (R)</b>	26	27	23	17	24	27	27	27	4
<b>Specimen 2944 (R)</b>	26	22	24	18	23	25	22	27	19

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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