



# Newborn Screening Quality Assurance Program

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

Quarterly Report

Quarter 1

February 2009

### INTRODUCTION

The Anti-HIV-1 proficiency testing (PT) panel for Quarter 1, 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 can be evaluated by not only challenging participants with specimens representing HIV-negative and positive serostatuses but also by offering specimens with antibodies against various HIV subclasses.

On January 20, 2009, we sent the Quarter 1 Anti-HIV-1 panel to 63 total participants. We received data reports from 51 participating laboratories by the designated deadline date. This report is the outcome of data reported for the Quarter 1, 2009 Anti-HIV-1 PT specimens. This quarterly report is distributed to all participants and to program colleagues by 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 1941-1945.

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 and one false positive result reported by the same laboratory using an in-house 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 and the next major allotment of HIV-1 DBS quality control specimens on April 13, 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

On National Black HIV/AIDS Awareness and Information Day, February 7, 2009, a statement was made by Dr. Anthony S. Fauci, Director of the National Institute of Allergy and Infectious Diseases, "One in 20 residents of Washington, D.C., a majority black city, is living with HIV, approximately the same proportion of people as in the sub-Saharan region of Africa. One in 50 D.C. residents has AIDS". ❖  
[http://www3.niaid.nih.gov/about/directors/news/BAAID\\_09.htm](http://www3.niaid.nih.gov/about/directors/news/BAAID_09.htm)



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## Quarter 1, 2009

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

Specimen Number	Expected Results	Reactive	Non-reactive	Not Reported
1941	Reactive	50	1	12
1942	Reactive	51	0	12
1943	Non-Reactive	0	51	12
1944	Reactive	51	0	12
1945	Non-Reactive	1	50	12

### 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	1
11	In House	1
12	Other (Please specify in detail)	3
15	Genetic Systems rLAV EIA (Bio-Rad)	14
20	bioMerieux Vironostika UniForm II Ag/AB	2
21	bioMerieux Vironostika Uni-Form II plus O	5
22	Genescreen HIV 1/2 V2	2
23	Genescreen Plus HIV Ag/Ab (BioRad)	0
24	Murex HIV 1.2.0 (Abbott)	13
25	Murex HIV Ag/Ab Combination (Abbott)	1
26	Recombinant HIV 1/2, Russia	4
27	Tecnosuma (Cuba) UMELISA HIV 1+2	2
28	CombiBest Anti-HIV 1, 2 DCM, Russia	2
29	CombiBest 1/2, Ag/Ab, Russia	4
30	Anti-HIV Unif, Russia	5
31	Dade Behring Enzygnost Anti-HIV 1/2 Plus O	1
33	UniBest HIV 1,2 AB, Russia	7
34	Q-Preven HIV 1+2, DBS, Brazil	0
39	Genescreen Ultra HIV AG-AB	3
	Total	70

## Quarter 1, 2009

**TABLE 3. Quarter 1, 2009, Summary of Errors by Screening Method**

Method Code	Kit Source	1941 (R) FN	1942 (R) FN	1943 (NR) FP	1944 (R) FN	1945 (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	1				1
12	Other (Please specify in detail)					
	<b>TOTAL</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>
	<b>False negative results = 1</b>					
	<b>False positive results = 1</b>					

**Quarter 1, 2009**

**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)	14
32	Cambridge Biotech HIV-1 WB Kit (Maxim)	2
35	OraSure HIV-1 WB Kit	1
36	Bio-Rad New LAV Blot I	3
37	Genelab Diagnostics HIV 2.2 WB	2
38	ImmunoComb II HIV 1&2 CombFirm (Orgenics)	1
12	Other (MP Diagnostics HIV Blot 2.2)	0
Total		23

**Tables 5: Reported Frequency of Bands for Reactive Specimens 1941, 1942, and 1945 (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 1941 (R)</b>	21	21	21	8	21	22	22	10	3
<b>Specimen 1942 (R)</b>	22	22	21	15	22	23	23	23	8
<b>Specimen 1945 (R)</b>	22	20	21	19	21	23	19	23	17