



# Newborn Screening Quality Assurance Program

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

Quarterly Report

Quarter 3

September 2010

### INTRODUCTION

The Anti-HIV-1 proficiency testing (PT) panel for Quarter 3, 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 July 19, 2010, we sent the Quarter 3 Anti-HIV-1 panel to 79 total participants. We received data reports from 50 participating laboratories by the designated deadline date. This report is the outcome of data reported for the Quarter 3, 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 3041-3045.

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 three false negative, one false positive, and six indeterminate results this quarter. Specimen 3043 was a 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 October 12, 2010. ❖

### Future Meetings:

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

November 5, 2010  
13th Annual HIV Symposium: Fine Tuning a Good Thing. Nashville, TN

November 18 - 20, 2010  
ANAC 2010 National Conference. Reno, NV.

December 2 - 4, 2010  
CME: The Medical Management of HIV/AIDS. San Francisco, CA.

### SPOTLIGHT

Results of the CAPRISA 004 trial, the safety and effectiveness study of an antiretroviral microbicide (tenofovir gel), were released at the XVIIIth International AIDS Conference in Vienna on Tuesday, 20 July 2010. It showed that women in the tenofovir gel group had a 39% lower risk of being infected with HIV. Read more at <http://www.caprissa.org>.



Direct inquiries to:  
Centers for Disease Control and Prevention (CDC)  
4770 Buford Highway, NE, MS/F43  
Atlanta, GA 30341-3724

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

Phone : 770-488-7897  
FAX: 770-488-4255  
E-mail: [NMeredit@cdc.gov](mailto:NMeredit@cdc.gov)

Editor : Nancy K. Meredith  
Production: Connie Singleton



**Anti-HIV-1 PT Report  
Quarter 3, 2010**

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

Specimen Number	Expected Results	Reactive	Non-reactive	Indeterminate	Not Reported
3041	Non-Reactive	1	51	0	27
3042	Reactive	52	0	0	27
3043	Reactive	44	3	5	27
3044	Non-Reactive	0	51	1	27
3045	Reactive	52	0	0	27

**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	2
12	Other (Please specify in detail)	7
15	rLAV EIA (Bio-Rad)	7
20	bioMerieux Vironostika UniForm II Ag/AB	5
21	bioMerieux Vironostika Uni-Form II plus O	4
22	Genescreen HIV 1/2 V2	3
23	Genescreen Plus HIV Ag/Ab (BioRad)	2
24	Murex HIV 1.2.0 (Abbott)	5
25	Murex HIV Ag/Ab Combination (Abbott)	5
26	Recombinant HIV 1/2, Russia	3
27	Tecnosuma (Cuba) UMELISA HIV 1+2	2
28	CombiBest Anti-HIV 1, 2 DCM, Russia	2
29	CombiBest 1/2, Ag/Ab, Russia	0
30	Anti-HIV Unif, Russia	11
31	Dade Behring Enzygnost Anti-HIV 1/2 Plus O	0
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	4
41	Bio-Rad HIV-1/Hiv-2 plus O EIA	2
<hr/>		Total 76

**Anti-HIV-1 PT Report  
Quarter 3, 2010**

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

Primary and Secondary screens methods	3041		3042		3043		3044		3045	
	FP	IND	FN	IND	FN	IND	FP	IND	FN	IND
10 Fujirebio Serodia-HIV 1,2						1				
15 Genetic Systems rLAV EIA (Bio-Rad)					1	1				
20 bioMerieux Vironostika UniForm 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)										
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						1				
30 Anti-HIV Unif, Russia	1							1		
31 Dade Behring Enzygnost Anti-HIV 1/2 Plus O										
32 Unibest HIV 1,2 AB, Russia										
34 Q-Preven HIV 1+2, DBS, Brazil						1				
11 In House										
12 Other					1					
<b>False Neg =</b>	<b>3</b>				<b>3</b>	<b>5</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>
<b>False Pos =</b>	<b>1</b>									
<b>Indeterminant =</b>	<b>6</b>									
<b>Totals</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>3</b>	<b>5</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>

## 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)	10
32	Cambridge Biotech HIV-1 WB Kit (Maxim)	4
35	OraSure HIV-1 WB Kit	1
36	Bio-Rad New LAV Blot I	3
37	Genelab Diagnostics HIV 2.2 WB	1
42	MP Diagnostics HIV Blot 2.2	2
12	Other ( INNO-LIA HIV ½)	1
		Total 22

**Tables 5: Reported Frequency of Bands for Reactive Specimens 3042, and 3043 and 3045 (All methods included)**

<b>Total # Labs (22)</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 3042 (R)</b>	21	22	20	20	21	22	22	22	19
<b>Specimen 3043 (R)</b>	19	15	14	8	11	14	14	16	11
<b>Specimen 3045 (R)</b>	21	17	17	17	16	18	18	22	17

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**.

**CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)**  
**ATLANTA, GA 30341**

**Director**

Thomas R. Frieden, M.D., M.P.H.

**Acting Director**

**National Center for Environmental Health**

Christopher J. Portier, Ph.D.

**Director**

**Acting, Division of Laboratory Sciences**

Theodore J. Meinhardt, Ph.D.

**Chief**

**Newborn Screening and Molecular Biology Branch**

Carla Cuthbert, Ph.D.

**Chief Emeritus**

**Newborn Screening and Molecular Biology Branch**

W. Harry Hannon, Ph.D.



**Contributors:** Barbara W. Adam  
Carol Bell  
Dana Chafin  
Victor R. De Jesus, Ph.D.  
Paul Dantonio  
Marie C. Earley, Ph.D.  
Elizabeth M. Hall  
Christopher Haynes, Ph.D.  
L. Omar Henderson, Ph.D.  
Kristin Jones  
Sharon Kerr  
Francis Lee, Ph.D.  
Lixia Li, Ph.D.  
Timothy Lim, Ph.D.  
Joanne Mei, Ph.D.  
Nancy Meredith  
Shannon O'Brien  
David Simms  
Robert Vogt, Ph.D.  
Golriz Yazdanpanah  
Sherri Zobel  
Hui Zhou, Ph.D.

**Production:**

Sarah Brown  
Felicia Manning  
Teresa Moore  
Connie Singleton

**ASSOCIATION OF PUBLIC HEALTH LABORATORIES**  
**SILVER SPRING, MD 20910**



**President**

Patrick F. Luedtke, M.D., M.P.H.

**Co-Chairpersons, Newborn Screening and Genetics in Public Health Committee**

Cheryl Hermerath, M.B.A., DLM(ASCP), RM(NRCM)

Susan M. Tanksley, Ph.D.

**Chairman, Newborn Screening Quality Assurance Quality Control Subcommittee**

Gary Hoffman, B.S.

**INQUIRIES TO:**

*Nancy Meredith, Editor • Centers for Disease Control and Prevention (CDC)*

*Newborn Screening Quality Assurance Program • Mailstop F-43*

*4770 Buford Highway, N.E. • Atlanta, GA 30341-3724*

*Phone (770) 488-4582 • FAX (770) 488-4255 • E-mail: NMeredit@cdc.gov*