

# Newborn Screening Quality Assurance Program

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

Quarterly Report

Quarter 2

May 2014

### INTRODUCTION

The Anti-HIV-1 proficiency testing (PT) panel for Quarter 2, 2014, 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 14, 2014, we sent the Quarter 2 Anti-HIV-1 panel to 18 domestic and 13 international participants. We received data reports from 27 of the 31 participating laboratories by the designated deadline date. This report is the outcome of data reported for the Quarter 2, 2014, Anti-HIV-1 PT specimens and is distributed to all participants and to program colleagues upon request.

Each participant was asked to analyze the specimens for anti-HIV-1 with 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.

There were no false negative and no false positive assessments reported.

### PARTICIPANTS' RESULTS

Table 1 shows the overall frequency of reported reactive, non-reactive, and indeterminate screening results for specimens 21441-21445.

In Part 1 of the report, Table 2 shows the number of laboratories using EIA screening methods/kits both for the primary and secondary screens.

Table 3 provides the overall statistics from the enzyme immunoassay methods screening assay where  $N \geq 3$ .

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 on July 15, 2014. ❖

### CONFERENCES AND MEETINGS

The 2014 STD Prevention Conference will be held in collaboration with the 15th IUSTI World Congress and 2nd Latin American IUSTI-ALACITS Congress, June 9-12, 2014 in Atlanta, GA.

2nd International Conference on HIV/AIDS, STDs & STIs- 2014 Conference, October 27-29, Las Vegas, Nevada, USA. Website: <http://72.167.32.140/hiv-aids-std-conference-2014/> ❖



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: 770-488-4582  
FAX: 770-488-4255  
E-mail: [IWilliams1@cdc.gov](mailto:IWilliams1@cdc.gov)

Editors: Joanne V. Mei  
Irene S. Williams



## Anti-HIV-1 PT Report

Quarter 2, 2014

**TABLE 1: Frequency Distribution: Outcome of Final Interpretations (27 Laboratories)**

Specimen Number	Expected Results	Non- Reactive	Reactive	Indeterminate
21441	Non-Reactive	27	0	0
21442	Non-Reactive	27	0	0
21443	Non-Reactive	27	0	0
21444	Reactive	0	27	0
21445	Non-Reactive	27	0	0

### Part 1. SCREENING

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

Method Code	Kit Source	Participants
10	Fujirebio Serodia-HIV 1,2	1
11	In House	1
12	Other	5
12	Other (Murex 1.2.0)	3
27	Tecnosuma (Cuba) UMELISA HIV 1+2	1
40	Avioq HIV-1 Microeleisa Systems	11
41	Bio-Rad HIV-1/HIV-2 plus O EIA	1
	Total	<u>23*</u>

\*Note: Four laboratories did not report EIA data and reported final interpretations based on a Western Blot confirmatory test.

**TABLE 3: Overall statistics from the EIA methods screening assay (N≥3)**

METHOD	STATISTIC	SPECIMEN				
		21441	21442	21443	21444	21445
<b>Avioq HIV-1 Microelisa System (N=11)</b>	OUTLIERS	0	0	0	0	0
	MEAN	0.107	0.102	0.161	1.964	0.125
	SD	0.024	0.031	0.207	0.358	0.051
	UL 95%	0.153	0.163	0.566	2.665	0.225
	LL 95%	0.061	0.041	0.000	1.263	0.025
<b>Murex HIV 1.2.0 EIA (N=3)</b>	OUTLIERS	0	0	0	0	0
	MEAN	0.137	0.145	0.141	5.611	0.172
	SD	0.107	0.110	0.105	3.840	0.134
	UL 95%	0.347	0.359	0.348	13.138	0.435
	LL 95%	0.000	0.000	0.000	0.000	0.000

**PART 2. CONFIRMATORY****TABLE 4: Number of Confirmatory Methods Reported**

<b>Method Code</b>	<b>Kit Source</b>	<b>Participants</b>
12	DAVIH Blot	1
16	Genetic Systems HIV-1 WB Kit (Bio-Rad)	14
32	Cambridge Biotech HIV-1 WB Kit (Maxim) New	1
36	LAV Blot I (Bio-Rad)	2
37	Genelab Diagnostics HIV 2.2 WB	1
42	MP Diagnostics HIV Blot 2.2	1

Total: 20

**TABLE 5: Reported Frequency of Bands for Reactive Specimens (All Methods)**

<b>Total # Labs (20)</b>	<b>gp160</b>	<b>gp120</b>	<b>p66</b>	<b>p55</b>	<b>p51</b>	<b>gp41</b>	<b>p31</b>	<b>p24</b>	<b>p18</b>
	Number of Laboratories Finding Reactive Bands								
Specimen 21444 (R)	20	18	13	14	14	16	15	20	9

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**

Robin Ikeda, M.D., M.P.H.

**Director**

**Division of Laboratory Sciences**

James L. Pirkle, M.D., Ph.D.

**Chief**

**Newborn Screening and Molecular Biology Branch**

Carla Cuthbert, Ph.D.



**Contributors:** Barbara W. Adam  
Paul Dantonio  
Victor R. De Jesus, Ph.D.  
Marie C. Earley, Ph.D.  
Sharon Flores  
David Foreman  
Stephanie Foster  
Elizabeth M. Hall  
Christopher Haynes, Ph.D.  
Sarah Klass  
Francis Lee, Ph.D.  
Lixia Li, Ph.D.  
Timothy Lim, Ph.D.  
Daniel Mandel, Ph.D.  
Joanne Mei, Ph.D.  
Nancy Meredith  
Patrick Pickens  
Kelsey Sheard  
Jennifer Taylor, Ph.D.  
Robert Vogt, Ph.D.  
Irene Williams  
Golriz Yazdanpanah  
Hui Zhou, Ph.D.  
Sherri Zobel

**Production:** Sarah Brown  
Felicia Manning  
Connie Singleton

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



**President**

Christine Bean, Ph.D., M.B.A., MT(ASCP)

**Chairman, Newborn Screening and Genetics in Public Health Committee**

Susan M. Tanksley, Ph.D.

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

Patrick Hopkin, B.S.

**INQUIRIES TO:**

*Irene Williams, 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: IWilliams1@cdc.gov*