

# Newborn Screening Quality Assurance Program

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

Quarterly Report

Quarter 3

August 2015

### INTRODUCTION

The Anti-HIV-1 proficiency testing (PT) panel for Quarter 3, 2015, 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 14, 2015, we sent the Quarter 3 Anti-HIV-1 panel to 15 domestic and 11 international participants. We received data reports from 23 of the 26 participating laboratories by the designated deadline date. This report is the outcome of data reported for Quarter 3, 2015 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 antibodies 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 an evaluation.

No false-negative and no false-positive misclassifications were reported.

### PARTICIPANTS' RESULTS

Table 1 shows the overall frequency of reported reactive, non-reactive, and indeterminate screening results for specimens 31541-31545.

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

Table 3 provides the overall statistics for the screening EIA methods where  $N > 3$ .

In Part 2 of the report (Confirmatory testing), 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 October 6, 2015. ❖

### CONFERENCES AND MEETINGS

United States Conference on AIDS (USCA) – September 10-13, 2015. Marriott Marquis, Washington, DC.

3rd International Conference on HIV/AIDS, STDs and STIs- November 30 - December 02, 2015. Hilton Atlanta Airport, Atlanta, USA

National HIV Prevention Conference – December 6-9, 2015. Hyatt Regency Hotel, Atlanta, GA.

2016 HIV Diagnostics Conference- March 21-24, 2016. Hyatt Regency Hotel, Atlanta, GA.  
<http://hivtestingconference.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: [IWilliams1@cdc.gov](mailto:IWilliams1@cdc.gov)

Editor: Joanne V. Mei  
Irene S. Williams



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**TABLE 1: Frequency Distribution: Outcome of Final Interpretations (23 Laboratories)**

<u>Specimen Number</u>	<u>Expected Results</u>	<u>Non- Reactive</u>	<u>Reactive</u>	<u>Indeterminate</u>
31541	Non-Reactive	23	0	0
31542	Reactive	0	23	0
31543	Non-Reactive	22	0	1
31544	Non-Reactive	23	0	0
31545	Non-Reactive	22	0	1

### Part 1. SCREENING

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

<u>Method Code</u>	<u>Kit Source</u>	<u>Primary</u>	<u>Secondary</u>
11	In House	1	
12	Other	2	
27	Tecnosuma (Cuba) UMELISA HIV 1+2	3	
40	Avioq HIV-1 Microeleisa Systems	11	5
41	Bio-Rad HIV-1/HIV-2 plus O EIA	1	1
43	Murex® HIV-1.2.O. Diasorin	<u>2</u>	1
Total Number of Participants:		20*	

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

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**TABLE 3: Overall statistics from the EIA method screening assay (N<sub>≥</sub>3)**

METHOD	STATISTIC	SPECIMEN				
		31541	31542*	31543	31544	31545
Avioq HIV-1 Microelisa System (N=11)	MEAN	0.116	2.970	0.139	0.104	0.108
	SD	0.049	0.336	0.037	0.015	0.015
	%CV	42.8	11.3	26.7	14.5	13.5

\*One laboratory reported a value for Specimen 31542 outside of the range of linearity.

## PART 2. CONFIRMATORY

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

Method Code	Kit Source	Total Participants
12	DAVIH Blot	1
16	Genetic Systems HIV-1 WB Kit (Bio-Rad)	10
32	Cambridge Biotech HIV-1 WB Kit (Maxim)	2
35	OraSure HIV-1 WB Kit	1
36	New LAV Blot I (Bio-Rad)	1
37	Genelab Diagnostics HIV 2.2 WB	1
Total:		16

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

Total # Labs (00)	gp160	gp120	p66	p55	p51	gp41	p31	p24	p18
	Number of Laboratories Finding Reactive Bands								
Specimen 31542 (R)	16	16	15	11	12	16	15	16	6

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.

**Director**

**National Center for Environmental Health**

Patrick Breyse, Ph.D.

**Director**

**Division of Laboratory Sciences**

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

**Chief**

**Newborn Screening and Molecular Biology Branch**

Carla Cuthbert, Ph.D.



**Contributors:** Carter Asef  
Paul Dantonio  
Victor R. De Jesus, Ph.D.  
Marie C. Earley, Ph.D.  
Sharon Flores  
Stephanie Foster  
Elizabeth M. Hall  
Christopher Haynes, Ph.D.  
Kameron Khaksarfard  
Francis Lee, Ph.D.  
Lixia Li, Ph.D.  
Timothy Lim, Ph.D.  
Daniel Mandel, Ph.D.  
Joanne Mei, Ph.D.  
Gyliann Peña  
Kelsey Sheard  
Robert Vogt, Ph.D.  
Irene Williams  
Golriz Yazdanpanah  
Hui Zhou, Ph.D.  
Sherri Zobel

**Production:** Sarah Brown  
Felicia Manning  
Chinh Nguyen  
LoNeka Shockley

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



**President**

Judith C. Lovchik, Ph.D., D(ABMM)

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

Susan M. Tanksley, Ph.D.

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

Patricia R. Hunt, B.A. and Joseph Orsini, Ph.D.

**INQUIRIES TO:**

*Irene Williams, Editor • Centers for Disease Control and Prevention (CDC)*  
*Newborn Screening Quality Assurance Program • Mailstop F-24*  
*4770 Buford Highway, N.E. • Atlanta, GA 30341-3724*  
*Phone (770) 488-4582 • FAX (770) 488-4255 • E-mail: IWilliams1@cdc.gov*