

# Newborn Screening Quality Assurance Program

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

Quarterly Report

Quarter 4

December 2013

### INTRODUCTION

The Anti-HIV-1 proficiency testing (PT) panel for Quarter 4, 2013, 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 October 23, 2013, we sent the Quarter 4 Anti-HIV-1 panel to 18 domestic and 13 international participants. We received data reports from 29 of the 31 participating laboratories by the designated deadline date. This report is the outcome of data reported for the Quarter 4, 2013, 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 misclassifications and one false positive result was reported.

### PARTICIPANTS' RESULTS

Table 1 shows the overall frequency of reported reactive, non-reactive, and indeterminate screening results for specimens 41341-41345.

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 provides the overall statistics from the enzyme immunoassay methods screening assay where  $N > 3$ .

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 January 14, 2014. ❖

### CONFERENCES AND MEETINGS

2nd International Science Symposium on HIV & Infectious Diseases (HIV SCIENCE 2014) - To be held at the ACCORD Metropolitan Hotel, T Nagar, Chennai, India. Please visit the symposium website at <http://HIVSCIENCE.yrgcare.org> to learn more about the event

The 30th Annual Clinical Virology Symposium and Annual Meeting of the Pan American Society for Clinical Virology will be held April 27 - 30, 2014 at the Hilton Daytona Beach Oceanfront Resort, Daytona Beach, FL. For information visit <http://www.clinicalvirologysymposium.org/>



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**Anti-HIV-1 PT Report  
Quarter 4, 2013**

**TABLE 1: Frequency Distribution: Outcome of Final Interpretations (29 Labs)**

<b>Specimen Number</b>	<b>Expected Results</b>	<b>Non- Reactive</b>	<b>Reactive</b>	<b>Indeterminate</b>	<b>Not Reported</b>
41341	Non-Reactive	28	1	0	0
41342	Non-Reactive	29	0	0	0
41343	Reactive	0	29	0	0
41344	Reactive	0	29	0	0
41345	Non-Reactive	29	0	0	0

**Part 1. SCREENING**

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

<b>Method Code</b>	<b>Kit Source</b>	<b>Participants</b>
10	Fujirebio Serodia-HIV 1,2	1
11	In House	1
12	Other	6
27	Tecnosuma (Cuba) UMELISA HIV 1+2	2
40	Avioq HIV-1 Microeleisa Systems	14
41	Bio-Rad HIV-1/HIV-2 plus O EIA	1
Total		25*

\*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 screening methods where N>3**

Avioq HIV-1 Microelisa System (N=14)					
SPECIMEN ID	OUTLIERS	MEAN	SD	UL 95%	LL 95%
41341	0	0.118	0.034	0.184	0.051
41342	0	0.108	0.037	0.181	0.035
41343	0	3.034	0.389	3.797	2.271
41344	0	2.089	0.403	2.880	1.299
41345	0	0.133	0.036	0.203	0.063

**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)	14
32	Cambridge Biotech HIV-1 WB Kit (Maxim)	3
36	New LAV Blot I (Bio-Rad)	2
37	Genelab Diagnostics HIV 2.2 WB	1
		Total: 20

**TABLE 5: Reported Frequency of bands for Reactive Specimens by Western Blot**

<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>
Specimen 41343 (R)	20	20	19	17	18	20	19	19	9
Specimen 41344 (R)	20	19	16	16	15	17	18	20	13

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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