

# Newborn Screening Quality Assurance Program

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

Quarterly Report

Quarter 2

May 2016

### INTRODUCTION

The Anti-HIV-1 proficiency testing (PT) panel for Quarter 2, 2016, 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 5, 2016, we sent the Quarter 1 Anti-HIV-1 panel to 15 domestic and 12 international participants. We received data reports from 22 of the 27 participating laboratories by the designated deadline date. This report is the outcome of data reported for Quarter 2, 2016 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 presump-

tive positives. A final interpretation for each specimen must be submitted to receive an evaluation.

No false negative and two false positive misclassifications were reported.

### PARTICIPANTS' RESULTS

Table 1 shows the overall frequency of reported reactive, non-reactive, and indeterminate screening results for specimens 21641- 21645.

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 profi-

ciency testing specimens by July 12, 2016. ❖

### CONFERENCES AND MEETINGS

AIDS 2016 – 21st International AIDS Conference. July 17-22, 2016, Durban, South Africa.



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

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**TABLE 1: Frequency Distribution: Outcome of Final Interpretations (22 Laboratories)**

<u>Specimen Number</u>	<u>Expected Results</u>	<u>Non- Reactive</u>	<u>Reactive</u>	<u>Indeterminate</u>
21641	Non-Reactive	20	1	1
21642	Non-Reactive	21	1	0
21643	Reactive	0	22	0
21644	Reactive	0	22	0
21645	Non-Reactive	22	0	0

### 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	3
27	Tecnosuma (Cuba) UMELISA HIV 1+2	3	
40	Avioq HIV-1 Microeleisa Systems	11	8
41	Bio-Rad HIV-1/HIV-2 plus O EIA	1	
43	Murex® HIV-1.2.O. Diasorin	<u>1</u>	1
Total Number of Participants:		19*	

\*Note: Two laboratories did not report EIA data and reported final interpretations based on a Western Blot confirmatory test. Another laboratory did not report quantitative data for their EIA.

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

METHOD	STATISTIC	SPECIMEN				
		21641	21642	21643	21644	21645
Avioq HIV-1 Microelisa System (N= 11)	MEAN	0.101	0.116	2.979	1.671	0.124
	SD	0.014	0.025	0.458	0.441	0.023
	%CV	13.8	22.0	15.4	26.4	18.8

## PART 2. CONFIRMATORY

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

<u>Method Code</u>	<u>Kit Source</u>	<u>Total Participant</u>
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:	<u>15</u>

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

Total # Labs (16)		gp160	gp120	p66	p55	p51	gp41	p31	p24	p18
	Interpretation	Number of Laboratories Finding Reactive Bands								
<b>Specimen 21643(R)</b>	<b>Positive</b>	15	15	15	10	12	15	15	15	2
	<b>Weak Positive</b>	0	0	0	4	2	0	0	0	4
	<b>Negative</b>	0	0	0	1	1	0	0	0	7
	<b>Indeterminate</b>	0	0	0	0	0	0	0	0	2
<b>Specimen 21644(R)</b>	<b>Positive</b>	14	8	3	9	4	8	1	15	14
	<b>Weak Positive</b>	1	3	5	3	6	4	3	0	1
	<b>Negative</b>	0	1	4	3	5	1	8	0	0
	<b>Indeterminate</b>	0	3	3	0	0	2	3	0	0

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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