

Newborn Screening Quality Assurance Program

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

Quarterly Report

Quarter 2

May 2015

INTRODUCTION

The Anti-HIV-1 proficiency testing (PT) panel for Quarter 2, 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 April 13, 2015, we sent the Quarter 2 Anti-HIV-1 panel to 15 domestic and 11 international participants. We received data reports from 23 of the 27 participating laboratories by the designated deadline date. This report is the outcome of data reported for Quarter 2, 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.

One false negative misclassification was received for specimen 21541. One false positive assessment was reported for specimens 21542, 21543, and 21545 and two false positive assessments were reported for specimen 21544, for a total of five false positive misclassifications.

False-positive assessments should be monitored and kept as low as possible.

PARTICIPANTS' RESULTS

Table 1 shows the overall frequency of reported reactive, non-reactive, and indeterminate screening results for specimens 21541-21545.

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 July 20, 2015. ❖

CONFERENCES AND MEETINGS

8TH IAS Conference on HIV Pathogenesis, Treatment and Prevention. July 19-22, 2015 Vancouver, British Columbia, Canada



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

Editor: Joanne V. Mei
Irene S. Williams



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TABLE 1: Frequency Distribution: Outcome of Final Interpretations (25 Laboratories)

Specimen Number	Expected Results	Non- Reactive	Reactive	Indeterminate
21541	Reactive	1	24	0
21542	Non-Reactive	24	1	0
21543	Non-Reactive	24	1	0
21544	Non-Reactive	23	2	0
21545	Non-Reactive	23	1	1

Part 1. SCREENING

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

Method Code	Kit Source	Primary	Secondary
11	In House	1	
12	Other	2	3
27	Tecnosuma (Cuba) UMELISA HIV 1+2	3	
40	Avioq HIV-1 Microeleisa Systems	12	10
41	Bio-Rad HIV-1/HIV-2 plus O EIA	1	
43	Murex® HIV-1.2.O. Diasorin	<u>3</u>	2
Total Number of Participants:		22*	

*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_≥3)

METHOD	STATISTIC	SPECIMEN				
		21541	21542	21543	21544	21545
Avioq HIV-1 Microelisa System (N=12)	OUTLIERS	0	0	0	0	0
	MEAN	1.844	0.104	0.110	0.101	0.112
	SD	0.551	0.025	0.033	0.026	0.036
	UL 95%	2.923	0.154	0.175	0.152	0.183
	LL 95%	0.764	0.054	0.046	0.051	0.040
Tecnosuma UMELISA HIV 1+2 (N=3)	OUTLIERS	1	1	1	1	1
	MEAN	0.969	0.255	0.281	0.139	0.189
	SD	0.153	0.028	0.054	0.063	0.047
	UL 95%	1.269	0.310	0.386	0.262	0.281
	LL 95%	0.668	0.200	0.176	0.015	0.096
Murex® HIV-1.2.O (N=3)	OUTLIERS	0	0	0	0	0
	MEAN	5.700	0.113	0.134	0.108	0.113
	SD	3.738	0.058	0.056	0.042	0.057
	UL 95%	13.027	0.227	0.245	0.191	0.224
	LL 95%	0.000	0.000	0.023	0.025	0.001

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)	11
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:		17

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 21541 (R)	17	12	6	14	10	11	5	17	16

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

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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.
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
Iris Landers
Felicia Manning
LoNeka Shockley

ASSOCIATION OF PUBLIC HEALTH LABORATORIES
SILVER SPRING, MD 20910

President

Dan Rice, DrPH, MS.

Chairman, Newborn Screening and Genetics in Public Health Committee

Susan M. Tanksley, Ph.D.

Chairman, Newborn Screening Quality Assurance Quality Control Subcommittee

Patrick Hopkins, 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