



Newborn Screening Quality Assurance Program

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

Quarterly Report

Quarter 4

November 2009

INTRODUCTION

The Anti-HIV-1 proficiency testing (PT) panel for Quarter 4, 2009 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 13, 2009, we sent the Quarter 4 Anti-HIV-1 panel to 83 total participants. We received data reports from 48 participating laboratories by the designated deadline date. This report is the outcome of data reported for the Quarter 4, 2009 Anti- HIV-1 PT specimens. This quarterly report is distributed to all participants and to program colleagues upon request.

Each participant was asked to analyze the specimens for anti- HIV-1 using the assay schemes they routinely use and to report for each specimen the screening results along with results from any confirmatory assays performed for pre-

sumptive positives. A final interpretation for each specimen must be submitted to receive a grade. ❖

PARTICIPANTS' RESULTS

Table 1 shows the overall frequency of reported reactive and non-reactive screening results for specimens 4941-4945.

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 shows the summary of screening errors by method. There were 2 false negative and 4 false positive errors for Quarter 4, 2009.

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 and

the next major allotment of HIV-1 DBS quality control specimens on January 19, 2010.❖

Future Meetings:

2010 HIV Diagnostics Conference
Doubletree Hotel Universal
Orlando
Orlando, FL
March 24-26, 2010

19th Annual HIV Conference
Rosen Shingle Creek,
Orlando, Florida
May 14-15, 2010

XVIII International AIDS
Conference
Vienna, Austria
July 18-23, 2010

SPOTLIGHT

The red ribbon is an international symbol of AIDS awareness that is worn by people all year round and particularly on World AIDS Day, December 1, 2009 to demonstrate care and concern about HIV and AIDS, and to remind others of the need for their support and commitment.



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: NMeredith@cdc.gov

Editor : Nancy K. Meredith
Production: Connie Singleton



Quarter 4, 2009

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

Specimen Number	Expected Results	Reactive	Non-reactive	Indeterminate	Not Reported
4941	Reactive	48	0	0	35
4942	Non-Reactive	1	47	0	35
4943	Reactive	47	1	0	35
4944	Reactive	47	1	0	35
4945	Non-Reactive	3	45	0	35

Part 1. SCREENING

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

Method Code	Kit Source	Participants
10	Fujirebio Serodia-HIV 1,2	2
11	In House	2
12	Other (Please specify in detail)	8
15	Genetic Systems rLAV EIA (Bio-Rad)	13
20	bioMerieux Vironostika UniForm II Ag/AB	2
21	bioMerieux Vironostika Uni-Form II plus O	4
22	Genescreen HIV 1/2 V2	2
23	Genescreen Plus HIV Ag/Ab (BioRad)	0
24	Murex HIV 1.2.0 (Abbott)	18
25	Murex HIV Ag/Ab Combination (Abbott)	2
26	Recombinant HIV 1/2, Russia	2
27	Tecnosuma (Cuba) UMELISA HIV 1+2	1
28	CombiBest Anti-HIV 1, 2 DCM, Russia	0
29	CombiBest 1/2, Ag/Ab, Russia	0
30	Anti-HIV Unif, Russia	9
31	Dade Behring Enzygnost Anti-HIV 1/2 Plus O	1
33	UniBest HIV 1,2 AB, Russia	0
34	Q-Preven HIV 1+2, DBS, Brazil	0
39	Genescreen Ultra HIV AG-AB	10
Total		80

Quarter 4, 2009

TABLE 3. Quarter 4, 2009, Summary of Errors by Screening Method

Method Code	Kit Source	4941 (R) FN	4942 (NR) FP	4943 (R) FN	4944 (R) FN	4945 (NR) FP
10	Fujirebio Serodia-HIV 1,2					
15	Genetic Systems rLAV EIA (Bio-Rad)					
20	bioMerieux Vironostika UniForm II Ag/AB					
21	bioMerieux Vironostika Uni-Form II plus O		1	1	1	1
22	Genescreen HIV 1,2 V2					
23	Genescreen Plus HIV Ag/Ab (BioRad)					
39	Genescreen Ultra HIV Ag/Ab(BioRad)					1
24	Murex HIV 1.2.0 (Abbott)					
26	Recombinant HIV 1/2, Russia					
27	Tecnosuma (Cuba) UMELISA HIV 1+2					1
28	CombiBest Anti-HIV 1, 2 DCM, Russia					
29	CombiBest 1/2, Ag/Ab, Russia					
30	Anti-HIV Unif, Russia					
31	Dade Behring Enzygnost Anti-HIV 1/2 Plus O					
33	UniBest HIV 1,2 AB, Russia					
11	In House					
12	Other (Please specify in detail)					
TOTALS :						
False negative results = 2				1	1	
False positive results = 4			1			3

Quarter 4, 2009

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 (Bio-Rad)	11
32	Cambridge Biotech HIV-1 WB Kit (Maxim)	3
35	OraSure HIV-1 WB Kit	1
36	Bio-Rad New LAV Blot I	3
37	Genelab Diagnostics HIV 2.2 WB	2
12	Other (MP Diagnostics HIV Blot 2.2)	3
		Total 23

Tables 5: Reported Frequency of Bands for Reactive Specimens 4941, 4943, and 4944 (All methods included)

Total Labs (23)	160	120	66	55	51	41	31	24	18
	Number of Laboratories Finding Reactive Bands								
Specimen 4941 (R)	22	17	13	17	18	13	17	23	3
Specimen 4943 (R)	22	23	18	17	19	23	20	23	18
Specimen 4944 (R)	22	23	20	21	21	23	22	23	21

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

Howard Frumkin, M.D., Dr.P.H., M.P.H.

Director

Division of Laboratory Sciences

Eric J. Sampson, Ph.D.

Acting Chief

Newborn Screening and Molecular Biology Branch

W. Harry Hannon, Ph.D.



Contributors: Barbara W. Adam
Carol Bell
Dana Chafin
Paul Dantonio
Victor R. De Jesus, Ph.D.
Marie C. Earley, Ph.D.
Elizabeth M. Hall
L. Omar Henderson, Ph.D.
Sharon Kerr
Francis Lee, Ph.D.
Lixia Li, Ph.D.
Timothy Lim, Ph.D.
Zuzheng (Roy) Luo
Joanne Mei, Ph.D.
Nancy Meredith
Hien Nguyen
Shannon O'Brien
David Simms
Sherri Stevens
Robert Vogt, Ph.D.
Golriz Yazdanpanah
Hui Zhou, Ph.D.

Production: Sarah Brown
Felicia Manning
Teresa Moore
Connie Singleton



ASSOCIATION OF PUBLIC HEALTH LABORATORIES
SILVER SPRING, MD 20910

President

Susan U. Neill, Ph.D., M.B.A.

Chairman, Newborn Screening and Genetics in Public Health Committee

Cheryl Hermerath, M.B.A., DLM(ASCP), RM(NRM)

Chairman, Newborn Screening Quality Assurance Subcommittee

Gary Hoffman, BS

INQUIRIES TO:

Nancy Meredith, 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: NMeredith@cdc.gov