Newborn Screening Quality Assurance Program

anti-HIV-1 Antibodies in Dried Blood Spots Proficiency Testing Program (HIVPT)

In co-sponsorship with Association of Public Health Laboratories (APHL)
Provided by the Newborn Screening and Molecular Biology Branch
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Quarterly Report
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Report Authorization

This report has been reviewed and authorized by Dr. Joanne Mei, Laboratory Chief, Newborn Screening Quality Assurance Program.

Confidentiality Statement

NSQAP participant information and evaluations are strictly confidential and shared only with individual participants, unless written authorization for release is received.

Introduction

This report summarizes data collected within the specified period for the Quarter 1, 2020, anti-HIV-1 Antibodies in dried blood spots (DBS) PT event. It is distributed to all participants, state laboratory directors, and program colleagues by request. The tables within this report provide certification profiles and distribution information for the HIVPT specimen panel, reported screening methods, confirmatory methods, and final interpretations. An evaluation of your submitted data is attached to this summary.

Certification of PT Specimens

Method and laboratory performance are evaluated by challenging participants with DBS specimens representing HIV-negative and positive serostatuses. Anti-HIV-1 Antibody screening and confirmatory tests should identify all HIV-positive specimens, regardless of subtype. Expected screening and confirmatory results, and final clinical assessments, are provided in Table 1.

Table 1. Expected Results – EIA (OD), Western Blot (Band Detection) and Final Interpretation

EIA – Avioq HIV-1 Microelisa System; Western Blot—Genetic Systems HIV-1 WB (Bio-Rad)

Specimen	OD	gp160	gp120	p65	p55/51	gp41	p40	p31	p24	p18	Final -Interpretation
2010401	0.099	N	N	N	N	N	N	N	N	N	N
2010402	0.102	N	N	N	N	N	N	N	N	N	N
2010403	2.919	P	P	P	WP	P	N	P	P	N	R
2010404	1.697	P	WP	N	P	WP	P	WP	P	N	R
2010405	2.153	P	WP	N	P	N	P	WP	P	N	R

Western Blot Band Detection
N = Negative
WP = Weak positive
P = Positive

Distribution of PT Specimens

On January 14, 2020 a PT panel of five individual DBS specimens was distributed to 11 domestic laboratories and 14 international laboratories.

Participant Results

Screening Data

We received data from 18 of the 25 participating laboratories by the reporting deadline. Each participant was asked to analyze the specimens for anti-HIV-1 Antibodies with the assay schemes they routinely use. Data submission included screening results, any confirmatory results performed based on presumptive positive screening results, and the analytic methods used for all testing.

Table 2 shows the number of laboratories using enzyme immunoassay (EIA) screening methods or kits for both primary and secondary methods. Table 3 provides the overall statistics for the screening EIA methods where $N \geq 3$.

Table 2. Number of EIA Screening Methods Reported; Includes Primary and Secondary Methods

Method Code Number	Kit Source	Primary*	Secondary
11	In House	3	1
40	Avioq HIV-1 Microelisa System	6	0
-	Other**	6	3

*Three laboratories did not report EIA data and reported final interpretations based on a Western Blot confirmatory test. One laboratory did not report a method.

**Other methods include:
ELISA methods
Bio-Rad GS HIV Combo Ag/Ab EIA
Imunoscreen HIV 1/2 Ag/Ab - SS
Siemens Centaur
AiD HIV 1+2 Ag/Ab ELISA plus
Abbott architect HIV Ag/Ab kit
Genetic Systems™ HIV-1/HIV-2 PLUS O EIA (Bio-Rad)
Lab developed Luminex HIV-1/HIV-2 Immunoassay
GeeniusTM HIV 1/2 Supplemental Assay BIORAD

Table 3. Overall Statistics (units OD) (N≥3)

Screening Method: Avioq HIV-1 Microelisa System (N=6)

Statistics	Specimen 2010401	Specimen 2010402	Specimen 2010403	Specimen 2010404	Specimen 2010405
Mean	0.118	0.114	4.030	2.906	3.291
SD	0.072	0.058	2.549	1.784	1.914

Confirmatory Data

Twelve laboratories reported using Western Blot (WB) antibody analysis as either a screening or confirmatory method to detect anti-HIV-1 antibodies. Table 4 shows the number of laboratories using each WB kit source. Tables 5a-c show the frequency of WB bands for each of the PT specimens that were reactive.

Table 4. Western Blot Confirmatory Methods Reported

Method Code Number	Kit Source	Secondary
16	Genetic Systems HIV-1 WB Kit (Bio-Rad)	5
32	Cambridge Biotech HIV-1 WB Kit (Maxim)	3
36	New LAV Blot I (Bio-Rad)	3
-	Other	1

Frequency of Western Blot Bands for Reactive Specimens (All WB Methods)

5a. Number of Laboratories Finding Reactive Bands for Specimen 2010403 (N=12)

Interpretation	gp160	gp120	gp66	gp55/51	gp41	p40	p31	p24	p18
Positive	12	11	8	11	1	11	11	1	12
Weak Positive	0	0	4	1	3	1	0	3	0
Negative	0	1	0	0	4	0	1	6	0
Indeterminate	0	0	0	0	1	0	0	1	0

5b. Number of Laboratories Finding Reactive Bands for Specimen 2010404 (N=12)

Interpretation	gp160	gp120	gp66	gp55/51	gp41	p40	p31	p24	p18
Positive	2	2	9	3	5	7	11	6	2
Weak Positive	5	5	1	7	1	3	1	4	5
Negative	1	4	2	1	2	1	0	0	1
Indeterminate	2	1	0	1	0	0	0	1	2

5c. Number of Laboratories Finding Reactive Bands for Specimen 2010405 (N=12)

Interpretation	gp160	gp120	gp66	gp55/51	gp41	p40	p31	p24	p18
Positive	11	2	3	8	3	6	8	11	3
Weak Positive	1	7	6	2	9	1	2	1	7
Negative	0	1	2	2	0	2	1	0	0
Indeterminate	0	1	1	0	0	0	0	0	1

Final Interpretations

A final interpretation for each specimen must be submitted to receive an evaluation. Table 6 provides the frequency of all participant interpretations.

Table 6. Frequency Distribution of Final Interpretations (17 Laboratories*)

Specimen Number	Expected Value	Non-reactive	Reactive
2010401	N	17	0
2010402	N	17	0
2010403	R	0	17
2010404	R	1	16
2010405	R	1	16

*One lab did not provide Final Interpretations.

Evaluations

Overall, participants reported two misclassifications.

Future Shipments

The Newborn Screening Quality Assurance Program will ship next quarter's PT specimens on June 23, 2020.

The content of this report may also be located on our website at:
https://www.cdc.gov/labstandards/nsqap_reports.html

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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