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 4, 2019, 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
41941	1.697	P	WP	P	WP	WP	N	P	P	N	Reactive
41942	2.153	P	WP	WP	P	WP	P	WP	P	WP	Reactive
41943	0.092	N	N	N	N	N	N	N	N	N	Non-reactive
41944	0.099	N	N	N	N	N	N	N	N	N	Non-reactive
41945	0.102	N	N	N	N	N	N	N	N	N	Non-reactive

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

Distribution of PT Specimens

On September 24, 2019 a PT panel of five individual DBS specimens was distributed to 11 domestic laboratories and 16 international laboratories.

Participant Results

Screening Data

We received data from 23 of the 27 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/kits both for the 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	5	0
43	Murex® HIV-1.2.0 Diasorin	2	1
-	Other**	9	3
-	*Total*	19	5

*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 Screening Method (N≥3)

Method: Avioq HIV-1 Microelisa System (N=5)

Statistics	Specimen 41941	Specimen 41942	Specimen 41943	Specimen 41944	Specimen 41945
Mean	2.982	3.508	0.124	0.123	0.124
SD	1.877	1.880	0.059	0.075	0.075

Confirmatory Data

Thirteen laboratories reported using Western Blot (WB) antibody analysis as either a screening or confirmatory method in the detection of anti-HIV-1 antibodies. Table 4 shows the number of laboratories using each WB kit source. Table 5 shows the Reported Frequency of Bands by WB for each of the PT specimens that tested positive.

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	2
-	*Total*	13

Table 5. Frequency of Western Blot Bands for Reactive Specimens (All Methods)

Number of Laboratories Finding Reactive Bands for Specimen 41941 (N=13)

Interpretation	gp160	gp120	gp66	gp55/51	gp41	p40	p31	p24	p18
Positive	13	7	3	9	5	4	9	13	4
Weak Positive	0	3	6	1	5	2	1	0	4
Negative	0	2	2	3	1	3	3	0	1
Indeterminate	0	1	1	0	2	0	0	0	2

Number of Laboratories Finding Reactive Bands for Specimen 41944 (N=13)

Interpretation	gp160	gp120	gp66	gp55/51	gp41	p40	p31	p24	p18
Positive	13	8	5	8	6	4	8	13	2
Weak Positive	0	4	3	3	5	3	3	0	4
Negative	0	0	4	2	1	2	2	0	4
Indeterminate	0	0	1	0	1	0	0	0	2

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 (23 Laboratories)

Specimen Number	Expected Value	Non-reactive	Reactive
41941	Reactive	0	23
41942	Reactive	0	23
41943	Non-Reactive	23	0
41944	Non-Reactive	23	0
41945	Non-Reactive	23	0

Evaluations

Overall, participants reported no misclassifications.

Future Shipments

The Newborn Screening Quality Assurance Program will ship next quarter's PT specimens on January 14, 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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