Newborn Screening Quality Assurance Program anti-HIV-1 Antibodies in Dried Blood Spots Proficiency Testing Program (HIVPT)

In co-sponsorship with the Association of Public Health Laboratories (APHL)
Provided by the Newborn Screening and Molecular Biology Branch
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REPORT AUTHORIZATION
Dr. Stanimila Nikolova, Laboratory Chief, Proficiency Testing and Reference Material reviewed and authorized this report.

CONFIDENTIALITY STATEMENT
NSQAP participant information and evaluations are strictly confidential and only available by accessing the NSQAP Participant Portal.

Introduction
This report summarizes data collected within the specified period for the Quarter 1, 2026, anti-HIV-1 Antibodies in dried blood spots (DBS) PT event. The tables within this report provide certification profiles and distribution information for the HIVPT specimen panel, reported screening methods, confirmatory methods, and final interpretations.

Specimen Consensus
A consensus of 80% of US laboratories, as long as 10 or more US laboratories report results, must be reached for a specimen to be evaluated. If fewer than 10 US laboratories report results for any one specimen, all submitted results are evaluated. NSQAP occasionally challenges cutoff levels by enriching samples near those levels. The NSQAP PT Committee closely reviews all specimen data. Specimens that are not evaluated are considered educational.

Because fewer than 10 domestic laboratories participated in this HIVPT event, all specimen results were evaluated.

Evaluations
NSQAP evaluated each reported result as “Acceptable” or “Unacceptable.” For each analyte and specimen, the participating laboratory’s assessment must match the CDC certified assessment to achieve an “Acceptable” evaluation. When assessments differ, the evaluation will be “Unacceptable.” NSQAP does not identify “Unacceptable” results as “false negative” or “false positive.” It is the responsibility of the laboratory to categorize “Unacceptable” results according to their protocols and policies.

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 Number	OD	gp160	gp120	p66	p55/51	gp41	p40	p31	p24	p18	Final Interpretation
20261004001	0.132	N	N	N	N	I	N	N	N	N	Non-Reactive
20261004002	0.154	N	N	N	N	I	N	N	N	N	Non-Reactive
20261004003	1.573	I	P	P	P	I	P	P	P	P	Reactive
20261004004	0.120	N	N	N	N	I	N	N	N	N	Non-Reactive
20261004005	2.864	P	P	P	P	P	P	P	P	P	Reactive

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

Distribution of PT Specimens

On January 28, 2026, NSQAP distributed a PT panel of five individual DBS specimens to 18 laboratories.

Participant Results

Screening Data
Participants were asked to submit their results through the NSQAP Participant Portal. We received data from 13 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 results based on confirmatory testing, and the analytic methods used for these analyses.

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≥3.

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

Kit Source	Primary
Enzyme Immunoassay Avioq HIV-1 Microelisa System	4
Other	7

Other methods include:
Alinity i HIV Ag/Ab Combo (CMIA), Abbott
Architect HIV Ag/Ab Combo (CMIA), Abbott
Imunoscreen HIV 1/2 Ag/Ab – SS, MBiolog Diagnósticos
Atellica CHIV Assay, Siemens
GS HIV-1/HIV-2 PLUS 0 EIA, Bio-Rad

Table 3. Overall Statistics (units OD) (N≥3)
Screening Method: Enzyme Immunoassay Avioq HIV-1 Microelisa System (N=4)

Specimen	Mean	SD
20261004001	0.194	0.142
20261004002	0.208	0.144
20261004003	3.613	2.010
20261004004	0.193	0.116
20261004005	5.771	3.254

Table 4. Western Blot Confirmatory Methods Reported

Method	Number of Users
Bio-Rad GS HIV-1 Western Blot	2
Bio-Rad New LAV Blot I	2
MP Diagnostics HIV Blot 2.2	1

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

Table 5a. Number of Laboratories Finding Reactive Bands for Specimen 20261004003 (N=5)

Interpretation	gp120	gp160	gp41	p18	p24	p31	p40	p5551	p66
Indeterminant	2	0	1	1	0	0	0	0	1
Negative	0	0	0	0	0	1	0	1	0
Positive	1	4	3	3	5	3	2	4	1
Weak Positive	2	1	1	0	0	1	1	0	3

Table 5b. Number of Laboratories Finding Reactive Bands for Specimen 20261004005 (N=5)

Interpretation	gp120	gp160	gp41	p18	p24	p31	p40	p5551	p66
Indeterminant	0	0	0	1	0	0	1	0	0
Negative	0	0	0	0	0	0	1	0	0
Positive	5	5	5	2	5	5	1	5	5
Weak Positive	0	0	0	1	0	0	0	0	0

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 (N=14)

Specimen	Expected Interpretation	Non-Reactive	Reactive	Indeterminant
20261004001	Non-Reactive	13	0	0
20261004002	Non-Reactive	13	0	0
20261004003	Reactive	1	12	0
20261004004	Non-Reactive	13	0	0
20261004005	Reactive	0	13	0

Evaluations

One participant reported an unacceptable interpretation for specimen 20261004003. All other interpretations agreed with CDC certified assessments.

Future Shipments

The Newborn Screening Quality Assurance Program will next ship HIV PT specimens on July 22, 2026.

Direct Inquiries

If you have any comments or questions about HIVPT analysis, contact Dr. Ernesto Gonzalez Reyes at *nmo3@cdc.gov*

For data reporting questions, contact the NSQAP at *nsqapdmt@cdc.gov*

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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