Newborn Screening Quality Assurance Program
Sickle Cell and Other Hemoglobinopathies
Proficiency Testing Program (HbPT)

In co-sponsorship with 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.

Acronym Glossary

Notation	Description	Notation	Description
DBS	dried blood spot	MS/MS	tandem mass spectrometry
FIA-MS/MS	flow injection analysis-tandem mass spectrometry	NSQAP	Newborn Screening Quality Assurance Program
Hb	hemoglobin	PCR	polymerase chain reaction
HPLC	high-performance liquid chromatography	PT	proficiency testing

Introduction

This report is the summary of HbPT data reported within the specified period for Quarter 1, 2026. The content includes specimen certification profiles; material distribution information; and frequency tables for presumptive phenotypes, clinical assessments, and reported methods.

Certification of PT Specimens

Four of the dried blood spot (DBS) specimens in this panel were prepared from purchased umbilical cord blood. The fifth, sent as an educational specimen, was prepared from a unit of adult donor blood. Table 1 lists the presumptive hemoglobin phenotypes and their presumptive clinical assessments.

Table 1. Specimen Certification

Specimen	Expected Presumptive Phenotype	Other Acceptable Phenotypes	Expected Presumptive Clinical Assessment	Other Acceptable Clinical Assessments
20261012001	SC	FSC	Hemoglobins S and C disease	No other acceptable
20261012002	FA + Bart's	FA, FAV	Alpha (α) Thalassemia	Normal - No abnormal Hb found, Alpha Thalassemia Silent Carrier, Hemoglobin V (variant)
20261012003	FAS	No other acceptable	Sickle Cell Carrier/Trait	No other acceptable
20261012004	FAC	No other acceptable	Hemoglobin C Carrier/Trait	No other acceptable
20261012005	FA + Bart's	FA, FAV	Alpha (α) Thalassemia	Normal - No abnormal Hb found, Alpha Thalassemia Silent Carrier, Hemoglobin V (variant)

Distribution of PT Specimens

On January 28, 2026, NSQAP distributed a PT panel of five DBS specimens to 44 domestic and 83 international laboratories.

Participant Results

Participants reported results through the NSQAP Participant Portal. We received results from 114 participants by the data reporting deadline. Participants assayed all survey specimens by the analytical schemes they routinely use and reported for the presumptive phenotype, presumptive clinical assessment, and any other clinical classifications deemed consistent with their analytic results and program operations.

Evaluations were based on reported phenotypes and clinical assessments for each specimen. An “Acceptable” evaluation matched the CDC expected (or acceptable) result, while an “Unacceptable” evaluation indicated an inconsistency with the CDC result. Note that failure to follow instructions may result in unacceptable evaluations.

Table 2 shows the frequency distribution of reported presumptive clinical phenotypes along with the frequency of misclassifications for each specimen. Table 3 shows the frequency distribution of reported presumptive clinical assessments and the frequency of misclassifications for each specimen.

Specimen Consensus

A clinical assessment consensus of 80% of US laboratories is required for a specimen to be evaluated. If fewer than 10 US laboratories report results for any one specimen, all submitted results were evaluated. The NSQAP PT committee closely reviews all specimen data. NSQAP considers not evaluated specimens as educational.

Although all specimens included in this panel met the consensus criterion, only four of the specimens were evaluated. Specimen 20261012001 was prepared from adult blood and was sent only as an educational challenge.

Table 2. Frequency Distributions of Reported Presumptive Clinical Phenotypes

Specimen: 20261012001

Presumptive Clinical Phenotype	Phenotype Frequency	Educational Specimen, Not Evaluated
FSC	62	NA
Other*	48	NA
FS	1	NA
FA	1	NA
FAV	1	NA
FAC	1	NA

*Other reported phenotypes included SC (18 reports), SCF (8 reports) and SCa (4 reports), among others.

Specimen: 20261012002

Presumptive Clinical Phenotype	Phenotype Frequency	Correctly Classified Phenotype	Misclassified Phenotype
FA	72	72	0
FA + Bart's	38	38	0
Other	2	2	0
FAV	1	1	0
F	1	0	1

Specimen: 20261012003

Presumptive Clinical Phenotype	Phenotype Frequency	Correctly Classified Phenotype	Misclassified Phenotype
FAS	104	104	0
FSA	6	0	6
Other	2	2	0
FAV	1	1	0
FS	1	0	1

Specimen: 20261012004

Presumptive Clinical Phenotype	Phenotype Frequency	Correctly Classified Phenotype	Misclassified Phenotype
FAC	105	105	0
FAV	2	1	1
FA	2	0	2
Other	2	2	0
FSC	1	0	1
FCA	1	0	1
FC	1	0	1

Specimen: 20261012005

Presumptive Clinical Phenotype	Phenotype Frequency	Correctly Classified Phenotype	Misclassified Phenotype
FA	70	70	0
FA + Bart's	40	40	0
Other	2	2	0
FAV	1	1	0
F	1	0	1

Table 3. Frequency Distributions of Reported Presumptive Clinical Assessments

Specimen: 20261012001

Presumptive Clinical Assessment	Assessment Frequency	Educational Specimen, Not Evaluated
Hemoglobins S and C disease	94	NA
Other	6	NA
Unsatisfactory sample	5	NA
Sickle cell anemia (HbSS or HbSβ⁰ Thalassemia)	4	NA
Hemoglobin V (variant)	2	NA
Clinical Assessment not listed	1	NA
Aging bands	1	NA
Hemoglobin E/Beta Plus Thalassemia (HbE/β+ Disease)	1	NA

Specimen: 20261012002

Presumptive Clinical Assessment	Assessment Frequency	Correctly Classified Assessment	Misclassified Assessment
Normal - No abnormal Hb found	72	72	0
Alpha (α) Thalassemia	23	23	0
Alpha Thalassemia Silent Carrier	14	14	0
Other	3	3	0
Hemoglobin V (variant)	1	1	0
Aging bands	1	0	1

Specimen: 20261012003

Presumptive Clinical Assessment	Assessment Frequency	Correctly Classified Assessment	Misclassified Assessment
Sickle Cell Carrier/Trait	108	108	0
Other	4	3	1
Hemoglobin V (variant)	1	0	1
Hemoglobin S/Beta plus Thalassemia (HbSβ+ Disease)	1	0	1

Specimen: 20261012004

Presumptive Clinical Assessment	Assessment Frequency	Correctly Classified Assessment	Misclassified Assessment
Hemoglobin C Carrier/Trait	106	106	0
Normal - No abnormal Hb found	4	0	4
Other	2	2	0
Hemoglobin V (variant)	1	0	1
Hemoglobins S and C disease	1	0	1

Specimen: 20253012005

Presumptive Clinical Assessment	Assessment Frequency	Correctly Classified Assessment	Misclassified Assessment
Normal - No abnormal Hb found	72	72	0
Alpha (α) Thalassemia	22	22	0
Alpha Thalassemia Silent Carrier	15	15	0
Other	3	3	0
Hemoglobin V (variant)	1	1	0
Aging bands	1	0	1

Table 4. Total Specimen Testing Error by Testing Algorithm

IEF = Isoelectric focusing, CE = Capillary electrophoresis. “Mass spec” include FIA-MS/MS, MS Maldi-ToF, and LC-MS/MS

Primary Method	Secondary Method	Tertiary Method	Total Specimens	Presumptive Phenotype Errors	Presumptive Clinical Assessment Errors
HPLC	NA	NA	214	3	4
HPLC	IEF	NA	61	0	0
HPLC	CE	NA	10	0	0
HPLC	HPLC	NA	40	1	0
HPLC	HPLC	HPLC	5	0	0
IEF	HPLC	NA	51	0	2
IEF	NA	NA	35	2	1
IEF	IEF	NA	19	1	1
IEF	IEF	HPLC	5	0	0
CE	NA	NA	32	0	0
CE	CE	NA	15	0	0
CE	CE	CE	10	0	1
CE	HPLC	NA	8	0	0
PCR	HPLC	NA	10	1	0
Mass spec	NA	NA	36	5	0
Mass spec	HPLC	NA	14	0	0
Other	NA	NA	5	2	1

Evaluations

Overall, participants reported seven unacceptable phenotype assessments and seven unacceptable clinical assessments.

Future Shipments

The Newborn Screening Quality Assurance Program’s next shipment of HbPT specimens will be on July 22, 2026.

Acknowledgments

Four of the specimens for this program were prepared from umbilical cord blood purchased from LifeSouth Community Blood Centers, Inc., Gainesville, FL.

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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