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
Centers for Disease Control and Prevention
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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 is the summary of HbPT data reported within the specified period for Quarter 3, 2019. It is distributed to all participants, state laboratory directors, and program colleagues by request. The content includes specimen certification profiles, material distribution information, frequency tables for presumptive phenotypes, clinical assessments, and reported methods. An evaluation of your reported data is attached to this summary.

Certification of PT Specimens

The dried blood spot (DBS) specimens in this panel were prepared from purchased umbilical cord blood. Table 1 lists the hemoglobin presumptive phenotypes and their presumptive clinical assessments.

Table 1. Specimen Certification

Specimen	Expected Presumptive Phenotype	Accepted Presumptive Phenotype	Expected Presumptive Clinical Assessment	Accepted Presumptive Clinical Assessment
319H1	FAS	FAS	Hemoglobin S trait	-
319H2	FS	FSU, UFS, U	Hb SS disease	Hb S with an uncommon variant
319H3	FAC	FAC	Hemoglobin C trait	-
319H4	FA	FA	Normal-No abnormal Hb found	-
319H5	FA	FA	Normal-No abnormal Hb found	-

Distribution of PT Specimens

On June 25, 2019, a PT panel of five DBS specimens was distributed to to 46 domestic and 37 foreign laboratories.

Participant Results

We received data from 80 participants by the data reporting deadline. Participants assayed all survey specimens by the analytical schemes they routinely use and report for each specimen the presumptive phenotype, presumptive clinical assessment, and any other clinical classifications deemed consistent with their analytic results and program operations.

Report presumptive phenotypes and presumptive clinical assessments as directed on the Hemoglobinopathies Data Report Form to avoid misclassifications. A few laboratories received misclassifcations because directions were not followed for providing phenotypes using standard nomenclature and/or adding symbols to the phenotype.

Laboratories should:

- Report one presumptive phenotype derived from results of all methods used for each specimen. Supplement unusual phenotype reports with comments in the Phenotype Comments section of the HbPT Data Report Form.
- List the hemoglobins in the order of abundance using standard phenotypic nomenclature when reporting the phenotype.
- Not insert symbols or blank spaces into the presumptive phenotype nomenclature.
- Report presumptive clinical assessments not listed in the drop-down menu under the Comment section in order to receive credit for the overall score.

Tables 2a-e show the frequency distribution of participant reported presumptive clinical phenotypes along with the frequency of misclassifications for each specimen. Tables 3a-e show the frequency distribution of reported presumptive clinical assessments and the frequency of misclassifications for each specimen.

Table 2a. Frequency Distribution of Reported Presumptive Clinical Phenotypes
Specimen 319H1

Presumptive Clinical Phenotype	Phenotype Frequency	#Correctly Classified Phenotype	Misclassified Phenotype	Reporting instructions not followed
FAS	73	73	0	-
Other	7	3	1	3

Table 2b. Frequency Distribution of Reported Presumptive Clinical Phenotypes
Specimen 319H2

Presumptive Clinical Phenotype	Phenotype Frequency	#Correctly Classified Phenotype	Misclassified Phenotype	Reporting instructions not followed
FS	72	72	0	-
Other	8	5	0	3

Table 2c. Frequency Distribution of Reported Presumptive Clinical Phenotypes
Specimen 319H3

Presumptive Clinical Phenotype	Phenotype Frequency	#Correctly Classified Phenotype	Misclassified Phenotype	Reporting instructions not followed
FAC	72	72	0	-
Other	8	2	3	3

Table 2d. Frequency Distribution of Reported Presumptive Clinical Phenotypes
Specimen 319H4

Presumptive Clinical Phenotype	Phenotype Frequency	#Correctly Classified Phenotype	Misclassified Phenotype	Reporting instructions not followed
FA	77	77	0	-
Other	3	0	0	3

Table 2e. Frequency Distribution of Reported Presumptive Clinical Phenotypes
Specimen 319H5

Presumptive Clinical Phenotype	Phenotype Frequency	#Correctly Classified Phenotype	Misclassified Phenotype	Reporting instructions not followed
FA	77	77	0	-
Other	3	0	0	3

Table 3a. Frequency Distribution of Reported Presumptive Clinical Assessments

Specimen 319H1

Presumptive Clinical Assessment	Assessment Frequency	#Correctly Classified Assessment	Misclassified Assessment
Hemoglobin S trait	77	77	0
Other	3	2	1

Table 3b. Frequency Distribution of Reported Presumptive Clinical Assessments
Specimen 319H2

Presumptive Clinical Assessment	Assessment Frequency	#Correctly Classified Assessment	Misclassified Assessment
Hb SS disease	76	76	0
Other	6	3	3

Table 3c. Frequency Distribution of Reported Presumptive Clinical Assessments
Specimen 319H3

Presumptive Clinical Assessment	Assessment Frequency	#Correctly Classified Assessment	Misclassified Assessment
Hemoglobin C trait	75	75	0
Other	5	2	3

Table 3d. Frequency Distribution of Reported Presumptive Clinical Assessments
Specimen 319H4

Presumptive Clinical Assessment	Assessment Frequency	#Correctly Classified Assessment	Misclassified Assessment
Normal-No abnormal Hb found	80	80	0

Table 3e. Frequency Distribution of Reported Presumptive Clinical Assessments

Specimen 319H5

Presumptive Clinical Assessment	Assessment Frequency	#Correctly Classified Assessment	Misclassified Assessment
Normal-No abnormal Hb found	80	80	0

Total Specimen Error Frequency by Testing Algorithm

Table 4 shows the frequency of errors per testing algorithm for all specimens. Algorithms reported by less than three participants are not shown.

Primary	Secondary	Total Specimens	Presumptive Phenotype Errors	Presumptive Clinical Assessment Errors
Isoelectric Focusing		47	3	2
Isoelectric Focusing	Bio-Rad Screening HPLC	36	0	0
Bio-Rad Screening HPLC		159	0	0
Bio-Rad Screening HPLC	Isoelectric Focusing	55	0	3
Primus Ultra HPLC		15	0	1

*Methods are designated as “Other” when less than three participants report results for a given method. “Other” methods include:

IEC-HPLC

MS/MS

Capillarys—ALERE

Sebia capillarys Neonatal Haemoglobin

Evaluations

Overall, participants reported four Presumptive Phenotype misclassifications and seven Presumptive Clinical Assessment misclassifications.

Future Shipments

The Newborn Screening Quality Assurance Program will ship next quarter’s HbPT specimens on September 24, 2019.

Acknowledgments

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The content of this report may also be located on our website at:
http://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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