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 4, 2018. 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
418H1	FS	FSE, FSV	Hb SS disease	Hb S with an uncommon variant; Hb SE disease
418H2	FA		Normal – No abnormal Hb found	
418H3	FAC		Hemoglobin C trait	
418H4	FAS		Hemoglobin S trait	
418H5	FA		Normal – No abnormal Hb found	

Distribution of PT Specimens

On September 25, 2018 a PT panel of five DBS specimens was distributed to to 46 domestic and 29 foreign laboratories.

Participant Results

We received data from 70 participants by the data reporting deadline. Participants assayed all survey specimens by the analytical schemes they routinely use, and reported, for each specimen, the presumptive phenotype, presumptive clinical assessment, and any other clinical classifications they deem consistent with their analytic results and program operations.

Presumptive phenotypes and presumptive clinical assessments should be reported as directed on the Hemoglobinopathies Data Report Form to avoid point deductions from their overall score. Laboratories should:

- Report one presumptive phenotype derived from results of all methods used by their laboratory 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 their 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 points for the overall score.

Tables 2a-e show the frequency distribution of participant reported presumptive clinical phenotypes along 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 418H1

Presumptive Clinical Phenotype	Phenotype Frequency	#Correctly Classified Phenotype	Misclassified Phenotype	Not Reported
FS	64	64	0	0
Other	6	4	1	1

Table 2b. Frequency Distribution of Reported Presumptive Clinical Phenotypes
Specimen 418H2

Presumptive Clinical Phenotype	Phenotype Frequency	#Correctly Classified Phenotype	Misclassified Phenotype
FA	70	70	0

Table 2c. Frequency Distribution of Reported Presumptive Clinical Phenotypes
Specimen 418H3

Presumptive Clinical Phenotype	Phenotype Frequency	#Correctly Classified Phenotype	Misclassified Phenotype
FAC	68	68	0
Other	2	1	1

Table 2d. Frequency Distribution of Reported Presumptive Clinical Phenotypes
Specimen 418H4

Presumptive Clinical Phenotype	Phenotype Frequency	#Correctly Classified Phenotype	Misclassified Phenotype
FAS	68	68	0
Other	2	1	1

Table 2e. Frequency Distribution of Reported Presumptive Clinical Phenotypes
Specimen 418H5

Presumptive Clinical Phenotype	Phenotype Frequency	#Correctly Classified Phenotype	Misclassified Phenotype
FA	70	70	0

Table 3a. Frequency Distribution of Reported Presumptive Clinical Assessments

Specimen 418H1

Presumptive Clinical Assessment	Assessment Frequency	#Correctly Classified Assessment	Misclassified Assessment	Not Reported
Hb SS Disease	65	65	0	0
Other	5	2	1	2

Table 3b. Frequency Distribution of Reported Presumptive Clinical Assessments

Specimen 418H2

Presumptive Clinical Assessment	Assessment Frequency	#Correctly Classified Assessment	Misclassified Assessment
Normal – No abnormal Hb found	70	70	0

Table 3c. Frequency Distribution of Reported Presumptive Clinical Assessments

Specimen 418H3

Presumptive Clinical Assessment	Assessment Frequency	#Correctly Classified Assessment	Misclassified Assessment
Hemoglobin C trait	70	70	0

Table 3d. Frequency Distribution of Reported Presumptive Clinical Assessments

Specimen 418H4

Presumptive Clinical Assessment	Assessment Frequency	#Correctly Classified Assessment	Misclassified Assessment
Hemoglobin S trait	70	70	0

Table 3e. Frequency Distribution of Reported Presumptive Clinical Assessments

Specimen 418H5

Presumptive Clinical Assessment	Assessment Frequency	#Correctly Classified Assessment	Misclassified Assessment
Normal – No abnormal Hb found	70	70	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	Tertiary	Total Specimens	Presumptive Phenotype Errors	Presumptive Clinical Assessment Errors
Isoelectric Focusing			25	2	1
Isoelectric Focusing	Bio-Rad Screening HPLC		45	1	0
Isoelectric Focusing	Primus Ultra 2 HPLC		25	0	0
Bio-Rad Screening HPLC			95	0	0
Bio-Rad Screening HPLC	Isoelectric Focusing		65	0	0

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

IEC-HPLC

MS/MS

Capillarys—ALERE

Sebia capillarys Neonatal Haemoglobin

Evaluations

Overall, participants reported three Presumptive Phenotype misclassifications and one Presumptive Clinical Assessment misclassification.

Future Shipments

The Newborn Screening Quality Assurance Program will ship next quarter’s HbPT specimens on January 15, 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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