Proficiency Testing Assay Instructions for Sickle Cell Disease and Other Hemoglobinopathies (HbPT)

CAUTION

These specimens are made from umbilical cord bloods and have not been tested for hepatitis B, HIV, hepatitis C, or other pathogens. Because no test method offers complete assurance that these or other infectious agents are absent, treat all specimens as potentially infectious and follow universal pre-cautions. For more information on bloodborne pathogens visit https://www.cdc.gov/niosh/topics/bbp/

SPECIMEN QUALITY STATEMENT

NSQAP strives to create specimens that mimic newborn dried blood spots. Prepared specimens have been certified and may depart from established visual criteria for assessing specimen quality. These specimens are fit for the purposes of proficiency testing.

CONFIDENTIALITY STATEMENT

NSQAP participant information and evaluations are confidential and shared only with individual participants, unless written authorization for release is received.

ASSAYING AND REPORTING INSTRUCTIONS

1. Inspect all proficiency testing (PT) specimens upon receipt. If a panel is incomplete or contains unlabeled specimens, request a new panel within 48 hours. Send the following information to NSQAPDMT@cdc.gov: laboratory code number, PT Panel Type, Specimen Number(s), and reason for requesting new panel.
2. Refrigerate the enclosed specimens at 4◦C upon receipt if storage is necessary.
3. Handle these specimens as routine specimens. Assay them as part of your normal daily workload.

   Participating laboratories must generate and submit their own results and must not share NSQAP PT test results or specimens with any other laboratory under ANY circumstance, even if the laboratory normally sends specimens to referral laboratories for routine or confirmatory testing. Participants found to have falsified or shared results will be barred from participation in the NSQAP PT program.
4. Punch all dried blood disks for analysis from within the blood spots on the specimen cards.
5. Report HbPT data in the NSQAP Participant Portal at: https://nbs.dynamics365portals.us/ Go to Biochemical PT in the main menu and proceed to HbPT Data Entry in the dropdown menu.
6. Every enclosed specimen represents a full-term (> 2500 g) baby 24 hours of age who is on no medication, has not had a transfusion, and has had sufficient intake of a protein and lactose-based diet for detection of any metabolic disorder.
7. Determine the significant hemoglobins (phenotypes) present in each specimen. A significant hemoglobin is any hemoglobin that you would include on a newborn screening specimen report. When reporting the phenotype, select the hemoglobins in the order of their abundance. If two hemoglobin variants are present in equal abundance, select the phenotype of greater clinical significance. Determine the presumptive clinical assessment of these specimens in a manner identical to that used for your routine unknown specimens.
8. If your laboratory uses one or more additional methods to re-analyze subsets (i.e., to confirm results) of newborn screening specimens, re-analyze those survey specimens that meet the criteria routinely used to select specimens for inclusion in the subsets.
9. Complete each assessment based on assay results and interpretation criteria established in your laboratory and report results from your primary screening method. If data are not reported, use the comment section to state why data were not reported and to state how specimens were used. If no data or explanations are provided, shipments will discontinue.

Late data will not be accepted for any reason. If data are not reported once within three events, your laboratory will be inactivated for this analyte program. To view dates for future shipments, see the NSQAP Shipping Schedule at: https://nbs.dynamics365portals.us/

For questions, send an email to NSQAPDMT@cdc.gov and include your laboratory code in the email subject line.