NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

Proficiency Testing Assay Instructions for Data-Reporting Website

CAUTION

The base serum and red blood cells used for preparing blood spot specimens at the Centers for Disease Control and Prevention (CDC) have been tested and found to be negative for Anti-HIV1,2 and O subtypes, Anti-HCV, HBsAg, Anti-HBc, and Chagas Disease (T.cruzi) by chemiluminescent immunoassay (ChLIA); HIV, HCV, HBV, and WNV by nucleic acid testing (NAT) and RPR (flocculation). Because no test method offers complete assurance that these or other infectious agents are absent, treat all specimens as potentially infectious and follow universal precautions. For more information on bloodborne pathogens, visit http://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 for the enriched analytes and may depart from established visual criteria for assessing specimen quality. These lab-created specimens are fit for the purposes of proficiency testing (PT).

CONFIDENTIALITY STATEMENT

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

ASSAY INSTRUCTIONS FOR FOLLOWING ANALYTES

- **Acylcarnitines** (µmol/L blood)
  - C0(L), C3, C3DC (derivatized), C3DC + C4OH (non-derivatized), C4, C4OH (derivatized), C5, C5:1, C5DC, C5OH, C6, C8, C10, C10:1, C10:2, C14, C14:1, C16, C16OH, C18, C18:1, C18OH
- **Amino Acids** (µmol/L blood)
  - Arg, Cit, Leu, Met, Phe, SUAC, Tyr, Val
- **Biotinidase** (qualitative reporting only)
- **Glucose-6-phosphate Dehydrogenase Deficiency** (qualitative reporting only)
- **Galactose-1-phosphate Uridylyltransferase** (qualitative reporting only)
- **Hormones + Total Galactose**
  - T4 (µg/dL serum), TSH (µIU/mL serum), 17OHP (ng/mL serum), TGal (mg/dL blood)
- **Immunoreactive Trypsinogen** (ng/ml blood)

ASSAYING AND REPORTING INSTRUCTIONS

1. Inspect all 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. Determine the presumptive clinical assessment of these specimens in a manner identical to that used for your routine unknown specimens.

   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.

6. All results must be reported in the units requested. Consult the conversion table for the correct analytes conversion factor at: https://wwwn.cdc.gov/NSQAP/Restricted/ConversionFactors.aspx

7. Complete each presumptive clinical assessment based on assay results, and enter the assessment code derived from your routine reporting scheme into the proper fields. Every enclosed specimen represents a full-term (>2500g) baby 24 hours of age who is no taking medication, has not had a blood transfusion, and has had sufficient intake of a protein and lactose-based diet for detection of any metabolic disorder.

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: http://www.cdc.gov/labstandards nsqap_resources.html.

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