Proficiency Testing Assay Instructions for Biochemical Analyte Programs

CAUTION

The human blood products used for preparing dried blood spots at the Centers for Disease Control and Prevention (CDC) were tested by FDA approved methods and found to be non-reactive for the following: hepatitis B surface antigen (HBsAg), HIV 1/2 Antibodies, HCV antibodies, Chagas Disease (*T.cruzi*), and Syphilis Serology. The blood products were non-reactive for HIV-1, HCV, and West Nile when tested by FDA approved RNA nucleic acid testing (NAT). Hepatitis B virus was non-reactive when tested by FDA licensed DNA NAT. 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 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 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 reports and evaluations are confidential and can be accessed only in the NSQAP Participant Portal.

ASSAY INSTRUCTIONS FOR FOLLOWING ANALYTES

- **Acylcarnitines** (µmol/L blood)
  C0(L), C2(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**
- **Glucose-6-phosphate Dehydrogenase**
- **Galactose-1-phosphate Uridyltransferase**
- **Hormones + 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 or specimens 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. Access the NSQAP Participant Portal at https://nbs.dynamics365portals.us/ . You will need a current Secure Access Management Services (SAMS) registration to access this portal. If you do not have access, your NSQAP primary contact must go to HELP in the main menu bar to access “Add/Remove User”. After the user information is submitted, the new user will receive an email invitation to register. Note that it may take up to 72 hours to receive the invitation.

6. Report all results in the units requested in the NSQAP Participant Portal.

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 not 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. Report data at least once per year for your laboratory to continue to receive materials. To the NSQAP Shipping Schedule go to: https://nbs.dynamics365portals.us/

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