NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

Quality Control Assaying and Reporting Instructions for Primary Quality Control Analytes

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 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 quality control testing.

ASSAY and REPORT INSTRUCTIONS INCLUDE THE FOLLOWING ANALYTES

- **Tandem MS 1 Quality Control** (µmol/L blood)
  C0, C2, C3, C3DC (derivatized), C4, C4OH (derivatized), C5, C5:1, C5DC, C5OH, C6, C8, C10, C10:1, C14, C 14:1, C16, C16OH, C18, C18OH, Arg, Cit, Gly, Leu, Met, Orn, Phe, SUAC, Tyr, Val, Creatine, Guanidinoacetic Acid, Creatinine, C20:0-lysophosphatidylcholine, C22:0-lysophosphatidylcholine, C24:0-lysophosphatidylcholine, C26:0-lysophosphatidylcholine

- **Galactose-1-phosphate Uridyltransferase Quality Control**

- **Thyroxine Quality Control** (µg/dL serum)

- **Thyroid-Stimulating Hormone Quality Control** (µIU/mL serum)

- **17 α-Hydroxyprogesterone** (ng/mL serum) and **Total Galactose** (mg/dL blood) **Quality Control**

- **Immunoreactive Trypsinogen Quality Control** (ng/mL blood)

STORAGE

Store QC materials at 4°C with desiccant up to one month; store reserves at -20°C±10°C with desiccant. Securely seal all zip-closures on bags for storage. (Exercise caution when removing sheets of blood spots from bags stored at -20°C ±10°C. Allow storage bags to acclimate to ambient temperature before opening.)

ASSAY AND REPORTING INSTRUCTIONS

*Participating laboratories must generate and submit their own results and must not share NSQAP QA test results or specimens with another laboratory under ANY circumstance, even if the laboratory normally sends specimens to referral laboratories for routine or confirmatory testing. Participants falsifying or sharing results or specimens will be barred from participation in the NSQAP QC program.*

1. Punch all dried blood disks for analysis from within the blood spots on the specimen cards.
2. During the transition phase from old to new QC lots, perform duplicate assays for the old and new QC lots in the same analytic runs. After the transition, use only the new QC lot.
3. Download the QC specimen certification data, Primary QC data entry form and data report form instructions from the NSQAP Resources website.
4. Carefully enter your results and method code number on the appropriate data-report form. Report duplicate results (not average) for one run per day for five days. Record all results as integers or decimals. Enter <LOD for values below your limit of detection.
5. Submitted forms that do not fulfill the laboratory information, method reporting, or result reporting requirements specified in the instructions will not be accepted.

6. Submit your completed Excel QC Data Report Form to NSQAP at NSQAPDMT@cdc.gov. If you have any QC questions, contact Irene Williams at NSQAPDMT@cdc.gov or 770-488-7024.

Late data will not be accepted for any reason. If data are not submitted at least once within two QC events, your laboratory will be inactivated for the analytes not reported. To view dates for future shipments, see the NSQAP Shipping Schedule at the NSQAP Resources website.

CDC QC materials supplement method or kit controls and are only intended for periodic use. They are not intended for routine or daily use.

Thank you for participating in our program for laboratory quality assurance. For questions, comments, and requests concerning these QC materials, call the NSQAP office at (770) 488-4582 or send an email to NSQAPDMT@cdc.gov and include your laboratory code in the email subject line.