NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

Quality Control Assaying and Reporting Instructions

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 show the following: hepatitis B surface antigen (HBsAg) negative, hepatitis B virus nucleic acid testing (NAT) negative, HIV 1&2 antibody negative, HIV NAT negative, hepatitis C virus antibody negative, hepatitis C virus NAT negative, and syphilis negative. In addition, all human red cell products were negative for Chagas Disease (T.cruzi) and West Nile Virus NAT. CFDNAQC dried blood spots are made using transduced cell lines grown in culture that are mixed with leukodepleted blood and serum to mimic a newborn sample. 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/healthcare/risk-factors/bloodborne-infectious-diseases.html.

SPECIMEN QUALITY STATEMENT

NSQAP strives to create specimens that mimic newborn dried blood spots (DBS). 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 (QC) testing.

QC ASSAY and REPORTING INSTRUCTIONS INCLUDE THE FOLLOWING ANALYTES

- **Tandem MS 1 QC** (µmol/L blood)
  C0, C2, C3, C3DC (derivatized), C3DC + C4OH (non-derivatized), C4, C4OH (derivatized), C5, C5:1, C5DC, C5OH, C6, C8, C10, C12, C14, C14:1, C16, C16OH, C18, C18OH, ALA, ARG, CIT, CRE, CRN, GLY, GUAC, LEU, MET, ORN, PHE, SUAC, TYR, VAL, ADO, dADO, C20-LPC, C22-LPC, C24-LPC, C26-LPC
- **Galactose-1-phosphate Uridyltransferase QC**
- **Thyroxine QC** (µg/dL serum)
- **Thyroid-Stimulating Hormone QC** (µIU/mL serum)
- **17 α-Hydroxyprogesterone** (ng/mL serum) **and Total Galactose** (mg/dL blood) **QC**
- **Immunoreactive Trypsinogen QC** (ng/mL blood)
- **Second-tier Maple Syrup Urine Disease and Phenylketonuria by LC-MS/MS** (µmol/L blood)
  Alloisoleucine, Isoleucine, Leucine, Phenylalanine, Tyrosine, Valine
- **Second-tier Methylmalonic/Propionic Acidemia and Homocystinuria by LC-MS/MS** (µmol/L blood)
  Malonic Acid, Methylmalonic Acid, Ethylmalonic Acid, 2-Methylcitric Acid, Total Homocysteine
- **Second-tier Congenital Adrenal Hyperplasia by LC-MS/MS** (µmol/L blood)
  17 α-Hydroxyprogesterone, 4-Androstenedione, Cortisol, 11-Deoxycortisol, 21-Deoxycortisol)
- **Lysosomal Storage Disorders QC** (µmol/hr/L)
  Galactoceramidase, Acid α-Glucosidase, α-L-Iduronidase, α-Galactosidase, β-Glucocerebrosidase, Acid Sphingomyelinase, Iduronate-2-Sulfatase
- **Cystic Fibrosis DNA QC**
  Transduced cell lines with pathogenic variants of Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene

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STORAGE

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.

Store the LSDQC and CFDNAQC materials at -20°C±10°C for both short– and long-term storage with desiccant until their expiration date. Minimize the number of freeze thaw cycles.

Store all other QC materials at 4°C with desiccant up to one month; store reserves at -20°C±10°C with desiccant until their expiration date.

ASSAY AND REPORTING INSTRUCTIONS

Participating laboratories must generate and submit their own results and must not share NSQAP QC 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. Inspect all QC specimens upon receipt. If a QC set is incomplete or contains unlabeled specimens, request a new set within 48 hours of receipt. Log into the NSQAP Participant Portal https://nbs.dynamics365portals.us/ . Click on HELP from the black bar, open a new request, include the reason for requesting a new QC set, and submit.
2. Punch all dried blood disks for analysis from within the blood spots on the specimen cards.
3. During the transition phase from old to new QC lots, perform duplicate assays for the old and new QC lots in the same analytical runs. After the transition, use only the new QC lot.
4. The NSQAP QC DBS materials provide participants with external controls to assess method performance over time. The controls provide continuity and transcend changes in production lots of routinely used method- or kit-control materials. The external QC materials are intended to supplement the participants' method or kit control materials at periodic intervals to allow participants to monitor the long-term stability of their assays. NSQAP QC materials are not a replacement for manufacturer kit controls or other daily QC, and should not be used for routine analysis.
5. Report results in the NSQAP Participant Portal.
   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 information is submitted, the new user will receive an email invitation to register. Note that it may take up to 72 hours for access after registration is complete.
6. Report duplicate results (not average) for each lot for five different runs. Any deviation from this criteria will not be accepted. Record all results as integers or decimals. Enter <LOD for values below your limit of detection.Report all results in the units requested in the NSQAP Participant Portal.
   CFDNA QC does not reqiure result reporting.
7. QC specimen certification data are also available for reference in the portal.
   QC analyte concentrations have been characterized using analytical methodologies used at CDC and should not be used as target values. Participants should establish their own analyte statistics by testing the specimens with their own method to determine assay performance.

Late data will not be accepted for any reason. Except for CFDNA QC, your laboratory must report results at least once per year for your QC programs to remain enrolled and to continue to receive materials. Failure to report results will result in inactivation for the program(s).

To view the NSQAP QC Shipping Schedule go to: https://nbs.dynamics365portals.us/ and click on Calendar: Key Dates and Events.

Submit questions by logging into the NSQAP Participant Portal https://nbs.dynamics365portals.us/. Click on HELP from the black bar and open a new request.

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