

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 and found to be non-reactive for the following: hepatitis B surface antigen (HBsAg), HIV1/2 antibodies, hepatitis C viral antibodies, Chagas Disease (T.cruzi), Syphilis, and Zika Virus. 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 (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** ($\mu\text{mol/L}$ blood)
C0, C2, C3, C3DC (derivatized), C3DC + C4OH (non-derivatized), C4, C4OH (derivatized), C5, C5:1, C5DC, C5OH, C6, C8, C10, C12, C14, C 14:1, C16, C16OH, C18, C18OH, Ala, Arg, Cit, Gly, Leu, Met, Orn, Phe, SUAC, Tyr, Val, Creatine, Guanidinoacetic Acid, Creatinine, C24:0-lysophosphatidylcholine, C26:0-lysophosphatidylcholine
- **Galactose-1-phosphate Uridyltransferase QC**
- **Thyroxine QC** ($\mu\text{g/dL}$ serum)
- **Thyroid-Stimulating Hormone QC** ($\mu\text{IU/mL}$ 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** ($\mu\text{mol/L}$ blood)
Alloisoleucine, Isoleucine, Leucine, Phenylalanine, Tyrosine, Valine
- **Second-tier Methylmalonic/Propionic Acidemia and Homocystinuria by LC-MS/MS** ($\mu\text{mol/L}$ blood)
Malonic Acid, Methylmalonic Acid, Ethylmalonic Acid, 2-Methylcitric Acid, Total Homocysteine
- **Second-tier Congenital Adrenal Hyperplasia by LC-MS/MS** ($\mu\text{mol/L}$ blood)
17 α -Hydroxyprogesterone, 4-Androstenedione, Cortisol, 11-Deoxycortisol, 21-Deoxycortisol)
- **Lysosomal Storage Disorders QC** ($\mu\text{mol/hr/L}$)
Galactoceramidase, Acid α -Glucosidase, α -L-Iduronidase, α -Galactosidase, β -Glucocerebrosidase, Acid Sphingomyelinase

STORAGE

Securely seal all zip-closures on bags for storage. Exercise caution when removing sheets of blood spots from bags stored at $-20^{\circ}\text{C} \pm 10^{\circ}\text{C}$. Allow storage bags to acclimate to ambient temperature before opening.

Store the LSDQC materials at $-20^{\circ}\text{C} \pm 10^{\circ}\text{C}$ for both short- and long-term storage with desiccant until their expiration date.

Store all other QC materials at 4°C with desiccant up to one month; store reserves at $-20^{\circ}\text{C} \pm 10^{\circ}\text{C}$ 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. 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 analytical runs. After the transition, use only the new QC lot.
3. 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
4. Access the data-reporting 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 has the ability to add you as a portal user by logging into the portal, clicking HELP in the main menu bar, then clicking on Add/Remove User and entering the required user information. It may take up to 72 hours for the new user to receive an email invitation to register in the portal.
5. Report all results in the units requested in the data-reporting portal.
6. 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. If data are not submitted at least once within two consecutive QC events, your laboratory will be inactivated for the analyte programs not reported.

To view dates for future shipments, see the NSQAP Event Calendar on the main page of the data reporting portal.