

NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

Proficiency Testing Assay Instructions for Second-tier Congenital Adrenal Hyperplasia by LC-MS/MS (CAHPT)

(17 α -Hydroxyprogesterone, 4-Androstenedione, Cortisol, 11-Deoxycortisol, 21-Deoxycortisol)

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. 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.

CONFIDENTIALITY STATEMENT

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

ASSAYING AND REPORTING INSTRUCTIONS

1. Inspect all proficiency testing (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 a 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.
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.
5. The CAHPT Data Reporting is on the Participant Portal at: <https://nbs.dynamics365portals.us/>
6. Treat each specimen according to your standard procedure. Results above your enzyme immunoassay (EIA) screening cutoff should be verified by liquid chromatography tandem mass spectrometry (LC-MS/MS). Report values in ng/mL units for serum. Laboratories must use the algorithm (17OHP+4AD)/CORT. Include the cutoff ratio value for LS-MS/MS results. Materials also include 11D and 21D, however, these analytes are for information only and cannot be used to evaluate specimens. If another ratio or algorithm is used to evaluate specimens, your assessment may not agree with CDC's expected clinical assessment.
7. Every enclosed specimen represents a full-term (> 2500 g) baby 24 hours of age who is on no medication, has not had a transfusion, and has had sufficient intake of a protein and lactose-based diet for detection of any metabolic disorder.
8. If you cannot report results for any or all specimens, use the comment field to explain why. You must report results (or an explanation) for each specimen to stay enrolled in the program. If a specimen result (or explanation) is not reported, no credit will be issued for it in the scoring.

9. Upload the file to the Participant Portal as instructed.

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: <https://nbs.dynamics365portals.us/>

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