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 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 http://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 strictly 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.

4. Punch all dried blood disks for analysis from within the blood spots on the specimen cards.

5. Download the CAHPT Data Reporting form from our website at: http://www.cdc.gov/labstandards nsqap_resources.html

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) If your laboratory runs both of these methods, follow your algorithm for testing the specimens by LC-MS/MS. Report values in ng/mL units for serum. For LS-MS/MS method results, include the cutoff value and the clinical ratio equation used to determine the clinical assessment (e.g. (17OHP + Androstenedione)/Cortisol= clinical ratio).

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. Attach the file to an email and send to NSQAPDMT@cdc.gov. Include your laboratory code number in the subject line of your email.

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: http://www.cdc.gov/labstandards/nsqap_resources.html.

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