Proficiency Testing Assay Instructions for X-linked Adrenoleukodystrophy (XALDPT)

(24:0– and 26:0– Lysophosphatidylcholines)

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 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. Download the XALDPT Data Reporting form from our website at: http://www.cdc.gov/labstandards nsqap_resources.html
6. Every enclosed specimen represents a full-term (>2500g) 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.
7. Report final clinical assessment according to the testing algorithm for your laboratory. 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. Continual non-reporting will be reviewed and may result in inactivation from this program.
8. Complete all requested information on the data report form. Save the file for your records then attached 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.