

NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

Pilot Proficiency Testing Assay Instructions for Spinal Muscular Atrophy (SMAPT)

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 and may depart from established visual criteria for assessing specimen quality. **These specimens are fit for the purposes of pilot proficiency testing for the *SMN1* Exon 7 deletion only. These samples do NOT contain TREC.**

CONFIDENTIALITY STATEMENT

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

ASSAYING AND REPORTING INSTRUCTIONS

1. Inspect all pilot 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, Pilot 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 Pilot 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. Complete the pilot SMAPT Data Reporting via the NSQAP Portal.
6. Fill in ALL requested information on the pilot SMAPT Data Reporting page. Complete each assessment based on assay results and interpretation criteria established in your laboratory. Select the appropriate Assessment Code from the drop-down. A comment field is provided for specific comments about the assessment or the specimen that need to be communicated.
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. When all data have been entered and confirmed, click "Submit" to submit your data.

FEEDBACK INSTRUCTIONS

1. Follow the steps on the SMA Pilot PT Customer Service Feedback Form.
2. Attach the completed SMA Pilot PT Customer Service Form to an email and send to NSQAPDMT@cdc.gov.

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