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 show the following: hepatitis B surface antigen (HBsAg) negative, hepatitis B virus nucleic acid testing (NAT) negative, HIV 1&2 antibody negative, HIV NAT negative, hepatitis C virus antibody negative, hepatitis C virus NAT negative, and syphilis negative. In addition, all human red cell products were negative for Chagas Disease (T.cruzi) and West Nile Virus 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/healthcare/risk-factors/bloodborne-infectious-diseases.html.

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 (PT).

CONFIDENTIALITY STATEMENT

NSQAP participant reports and evaluations are confidential and can be accessed in the NSQAP Participant Portal.

ASSAYING AND REPORTING INSTRUCTIONS

1. Inspect all PT specimens upon receipt. If a panel is incomplete or contains unlabeled specimens, request a new panel within 48 hours of receipt. Log into the NSQAP Participant Portal https://nbs.dynamics365portals.us/ . Click on HELP from the black bar, open a new request, include the reason for requesting new panel, and submit.

2. Refrigerate the enclosed specimens at 4ºC ± 2ºC upon receipt if storage is necessary.

3. Handle these specimens as routine specimens. Assay them as part of your normal daily workload. Determine the presumptive clinical assessment of these specimens in a manner identical used for your routine unknown specimens.

   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 or specimens 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. Report results in the NSQAP Participant Portal.

   Access the NSQAP Participant 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 must go to HELP in the main menu bar to access "Add/Remove User." After information is submitted, the new user will receive an email invitation to register. Note that it may take up to 72 hours for access after registration is complete.

6. Report all results in the units requested in the NSQAP Participant Portal.

7. Every enclosed specimen represents a full-term (>2500g) baby 24 – 48 hours of age who is not taking medication, has not had a blood transfusion, and has had sufficient intake of a protein and lactose-based diet for detection of any metabolic disorder.

Late data will not be accepted. Your laboratory must report results at least once per year for all your PT programs to remain enrolled and to continue to receive materials in the following year. Failure to report results will result in inactivation for the program(s).

To view the NSQAP PT Shipping Schedule go to: https://nbs.dynamics365portals.us/ and click on Calendar: Key Dates and Events.

Submit questions by logging into the NSQAP Participant Portal https://nbs.dynamics365portals.us/. Click on HELP from the black bar and open a new request.

Revised June 2024