NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

Proficiency Testing Assay Instructions for
Cystic Fibrosis Variant Detection
(CFDNAPT)

CAUTION

These specimens are made from normal donors and donors that have *CFTR* variants of interest and have not been tested for hepatitis B, HIV, and hepatitis C. 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 and may depart from established visual criteria for assessing specimen quality. These specimens are fit for the purposes of proficiency testing for variants in the Cystic Fibrosis Transmembrane Conductance Regulator (*CFTR*) gene. This is a separate program from the routine IRT PT program. For clinical assessment purposes, assume that the IRT is above your program's regular or ultra-high cutoff so that all samples should be tested for *CFTR* variants.

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.

   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. 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. Fill in ALL requested information on the CFDNA PT Data Entry page. Complete each assessment based on assay results and interpretation criteria established in your laboratory. Select the appropriate alleles identified by your laboratory and the Assessment Code using the search 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 should be treated as 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.

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.