

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/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 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 information and evaluations are 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. Complete the CFDNA PT Reporting via the NSQAP Portal.
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.
8. When all data have been entered and confirmed, click "Submit" to submit your data.

Note: participants enrolled in the CFDNAPT Program will be moved to an inactive status if data is not reported for 3 consecutive quarters.

To view dates for future shipments, see the NSQAP Shipping Schedule at: <https://nbs.dynamics365portals.us/> For questions, send an email to NSQAPDMT@cdc.gov and include your **laboratory code** in the email subject line.