

6. After the analysis is complete, record (1) method codes (primary and secondary/confirmatory), (2) variant panel if not a commercial panel or deviations from a commercial panel, (3) regions sequenced if you are using a gene sequencing method, (4) when and how you use your secondary/confirmatory method, and (5) DNA extraction method on the data report form. Note: if you use legacy nomenclature when describing regions sequenced (ie. exons and introns), you must specify that you are using legacy nomenclature; otherwise, it will be assumed that you are using HGVS nomenclature.
7. Complete each assessment based on your assay results, and enter both the clinical assessment and genotype results into the designated area of the report form. 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 blood transfusion, and has had sufficient intake of a protein and lactose-based diet for detection of any metabolic disorder.
8. There is a limited amount of specimens available for this program. If data are not reported, provide an explanation of how the specimens were used and why no data were reported in the Comments section of the data report form. If no data or explanations are given, shipments will be discontinued.
9. Upload the file to the Participant Portal as instructed.

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: <https://nbs.dynamics365portals.us/> For questions, send an email to NSQAPDMT@cdc.gov and include your **laboratory code** in the email subject line.

CF METHOD CODE LIST

- CF1 - GenMark Cystic Fibrosis Genotyping
- CF3 - Luminex Molecular Diagnostics xTAG CF - ACMG only
- CF4 - Luminex Molecular Diagnostics CFTR IVD 39 v2
- CF5 - Luminex Molecular Diagnostics xTAG CF 60 v2
- CF6 - Luminex Molecular Diagnostics xTAG CF 71 v2
- CF7 - Luminex Platform and Laboratory Developed Test
- CF8 - Elucigene Diagnostics CF4v2
- CF9 - Elucigene Diagnostics CF29v2
- CF10 - Elucigene Diagnostics CF30v2
- CF11 - Elucigene Diagnostics CF-EU2v1
- CF12 - Abbott Molecular CF Genotyping Assay v3
- CF13 - Inno-LiPA Strip 17
- CF14 - Inno-LiPA Strip 19
- CF15 - Inno-LiPA Strips 17+19
- CF16 - Sequenom HerediT CF assay
- CF17 - Sequenom assays other than HerediT CF (MALDI-TOF Mass Spectrometry)
- CF18 - ViennaLab Diagnostics GmbH CF StripAssay, GER
- CF19 - ViennaLab Diagnostics GmbH CF StripAssay (4-410)
- CF20 - Allele-specific Oligonucleotide PCR
- CF21 - High Resolution Melt Technology
- CF22 - Real-time PCR Allelic Discrimination Assay (i.e. TaqMan)
- CF23 - In-house Amplification Refractory Mutation System
- CF24 - In-house single nucleotide primer extension assay (SNUPe)
- CF25 - PCR/Heteroduplex Analysis/Gel Electrophoresis
- CF26 - Capillary Electrophoresis
- CF27 - Amplification and Restriction Fragment Length Polymorphism Analysis (PCR-RFLP)
- CF28 - Amplification and Polyacrylamide Gel Electrophoresis (PCR-PAGE)
- CF29 - Next Gen Sequencing - Illumina MiSeqDx 139 Variant Assay
- CF30 - Next Gen Sequencing - Multiplicom Molecular Diagnostics CFTR MASTR v2
- CF31 - Next Gen Sequencing - Ion AmpliSeq CFTR Community Panel
- CF32 - All other gene sequencing protocols including Sanger and Next Gen
- CF33 - Astra Biotech CFcheck DE-31
- CF34 - Devyser CFTR Core
- CF19 - ViennaLab Diagnostics GmbH CF StripAssay (4-410)

CF35 - Agena Bioscience iPLEX Pro CFTR Panel (72 mutations)

CF36 - In-house Hydrolysis Probe Assay

CF37 - Swift Biosciences Accel-Amplicon CFTR Panel

CF99 - Other - Please specify

UTILIZATION OF SECONDARY/CONFIRMATORY METHODS

M1 - Secondary method confirms variants detected by the primary method (no new variants will be identified)

M2 - Secondary method confirms variants detected by the primary method and may find additional new variants in the secondary panel

M3 - Use both the primary and secondary methods to detect variants found on both panels

M4 - Other -please describe below

EXTRACTION METHODS

X1 - Qiagen QIAamp spin columns (manual or robotic)

X2 - Qiagen magnetic bead kit (EZ1 or BioSprint 96)

X3 - Qiagen Generation DNA Purification & DNA Elution Solutions (also sold as 5 Prime Easy PCR Solutions 1 & 2)

X4 - Sigma Aldrich Extract-N-Amp

X5 - in-house alkaline lysis prep

X6 - in-house boiling prep

X7 - in-house lysis boil prep

X8 - ViennaLab GenXtract

X9 - Perkin Elmer/Chemagen Chemagic kit

X10 - in-house Chelex method

X19 - Other-please describe below