TEST CHANGE

Cystic Fibrosis (CFTR) Expanded Variant Panel, Fetal

2013662, CF VAR FE

Specimen Requirements:	
Patient Preparation:	
Collect:	Fetal Specimen: Amniotic fluid. OR Cultured amniocytes: Two T-25 flasks at 80 percent confluency. ORof cultured CVS: Two T-25 flasksamniocytes at 80 percent confluency. *If the client is unable to culture amniocytes, this can be arranged by contacting ARUP Client Services at (800-)-522-2787. AND Maternal Whole Blood Specimen: Lavender (EDTA), pink (K2EDTA), yellow (ACD Solution A or B).
Specimen Preparation:	Amniotic Fluid: Transport 10 mL amniotic fluid in a sterile container. (Min: 5 mL). Cultured Amniocytes or CVS: Fill flasks with culture media. Backup cultures must be retained at the client's institution until testing is complete. Maternal Whole Blood Specimen: Transport 3 mL whole blood. (Min. 1 mL)
Transport Temperature:	Amniotic fluid, cultured amniocyts and cultured CVSCultured Amniocytes: CRITICAL ROOM TEMPERATURE. Must be received within 48 hours of shipment due to lability of cells. Maternal Whole Blood Specimen: Refrigerated.
Unacceptable Conditions:	Maternal Whole Blood Specimen: Plasma or serum. Specimens collected in sodium heparin, yellow (ACD solution), or lithium heparin tubes. Frozen specimens in glass collection tubes.
Remarks:	Maternal whole blood sample is recommended for proper test interpretation; order Maternal Cell Contamination, Maternal Specimen. Patient History Form is available on the ARUP Web site or by contacting ARUP Client Services.
Stability:	Fetal Specimen: Amniotic fluid, cultured amniocytes and cultured CVS: Room TemperatureAmbient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable Maternal Whole Blood Specimen: Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month
Methodology:	Matrix-Assisted Laser Desorption Ionization-Time of Flight (MALDI-TOF) Mass Spectrometry
Performed:	Sun-Sat
Reported:	7-10 days

Note:	The Cystic Fibrosis (CFTR) Expanded Variant Panel includes 23 pathogenic CFTR variants recommended by the American College of Medical Genetics for population carrier screening.
CPT Codes:	81220; 81265 Fetal Cell Contamination (FCC)
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Refer to report.~~Refer to report.~~

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.~~

Counseling and informed consent are recommended for genetic testing. Consent forms are available online.

Reference Interval:

By report