

HOTLINE: Effective December 15, 2020

New Test **3002096** **Tuberous Sclerosis Complex Panel, Sequencing and Deletion/Duplication, Fetal** **TSC NGS FE**

Available Now

Methodology: Massively Parallel Sequencing/Genomic Microarray (Oligo-based Array)
Performed: Varies
Reported: 2-4 weeks, if culture is required an additional 1 to 2 weeks is required for processing time

Specimen Required: Collect: **Fetal Specimen:** Four (4) T-25 flasks at 80 percent confluent of cultured amniocytes or cultured CVS. **If the client is unable to culture, this can be arranged by contacting ARUP Client Services at (800) 522-2787.**

AND **Maternal Cell Contamination Specimen:** Lavender (K₂EDTA), Pink (K₃EDTA), or Yellow (ACD Solution A or B).

Specimen Preparation: **Cultured Amniocytes or Cultured CVS:** Fill flasks with culture media. Transport four (4) T-25 flasks at 80 percent confluent of cultured cells filled with culture media. Backup cultures must be retained at the client's institution until testing is complete.

AND **Maternal Cell Contamination Specimen:** Transport 3 mL whole blood (Min: 1 mL)

Storage/Transport Temperature: **Culture Amniocytes or Cultured CVS:** CRITICAL ROOM TEMPERATURE. Must be received within 48 hours of shipment due to lability of cells.

Maternal Cell Contamination Specimen: Room temperature.

Stability (collection to initiation of testing): **Culture Amniocytes or Cultured CVS:** Ambient: 48 hours; Refrigerated: Unacceptable; Frozen: Unacceptable

Maternal Cell Contamination Specimen: Ambient: 72 hours; Refrigerated: 1 week; Frozen: Unacceptable

Reference Interval: By report

Interpretive Data:

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.

Note: Reported times are based on receiving the four T-25 flasks at 80 percent confluent. Cell culture time is independent of testing turn-around time. Maternal specimen is recommended for proper test interpretation. Order Maternal Cell Contamination.

Genes tested: *TSC1 TSC2*

CPT Code(s): 81405; 81406; 81407; 81265

New York DOH approval pending. Call for status update.

HOTLINE NOTE: Refer to the Test Mix Addendum for interface build information.