

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 99D1066287	(X3) Date Survey Completed 07/25/2024
Name of Provider or Supplier Centro De Genetica Clinica/Cgc Genetics	Street Address, City, State Rua Manuel Pinto De Azevedo Numero 173, Not Available, FN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A recertification onsite survey was conducted on 07/25/2024 and standard level deficiencies were cited.
D5311	Based on review of written procedures, client services manual, and interview with staff, the laboratory failed to define specimen storage (temperatures), stability, conditions for specimen transportation in their own written procedures for molecular testing. Findings included: 1. Review of the laboratory's molecular procedures (whole exome sequencing, multiplex ligation-dependent probe amplification, triplet repeat primed polymerase chain reaction, and Sanger sequencing) referred to a different procedure for sample handling (UNI-GEN-I-038). 2. Review of "Sample pre-registration procedure" (UNI-GEN-I-038) did not include extracted DNA specimen: a) storage and preservation (collection tube, temperatures), b) conditions for specimen transportation, c) acceptability/rejection criteria for storage, conditions for transport, and stability 3. Review of the client services manual for specimen handling instructions stated, "Shipping should be well conditioned and at room temperature" and for evening or weekend shipments, "Keep sample at room temperature away from sources of cold or heat." Refer to D5317. 4. During an interview on 07/25/2024 at 12: 17 pm, the quality manager and technical supervisor explained extracted DNA was the specimen type accepted for testing (from the U.S.) and it was submitted in an Eppendorf tube or cryotube. After review of the above procedures, the quality manager, technical supervisor, laboratory director and quality director confirmed the preanalytical requirements had not been defined.
D5317	Based on review of written procedures, client services manual, and interview with staff, the laboratory failed to ensure all preanalytical requirements were included in their client services manual. Findings included: 1. Review of the laboratory's molecular procedures had not defined specimen storage (temperatures), stability, conditions for specimen transportation for extracted DNA. Refer to D5311. 2. Review of the client services manual for specimen handling instructions stated, "Shipping should be well conditioned and at room temperature" and for evening or weekend

shipments, "Keep sample at room temperature away from sources of cold or heat." The client services manual did not define "room temperature" and "well conditioned" to avoid compromising specimen integrity. In addition, the client services manual did not include: a) storage and preservation (collection tube, temperatures), b) conditions for specimen transportation, c) acceptability/rejection criteria for storage, conditions for transport, and stability 4. During an interview on 07/25/2024 at 12:17 pm, the quality manager and technical supervisor explained extracted DNA was the specimen type accepted for testing (from the U.S.) and it was submitted in an Eppendorf tube or cryotube. After review of the above procedures, the quality manager, technical supervisor, laboratory director and quality director confirmed the preanalytical requirements had not been defined.