

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2279973	(X3) Date Survey Completed 03/21/2024
Name of Provider or Supplier Genetx Laboratory Llc	Street Address, City, State 11311 Richmond Avenue, Suite L107, Houston, TX	
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	The laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended.
D5317	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d)</p> <p>If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation, a review of the laboratory's records, and staff interview, the laboratory failed to provide written instructions to its clients for the labeling, transportation, and acceptability/rejection criteria of specimens for one of one test performed by the laboratory in 2024. Findings include: 1. Surveyor observation of the laboratory on 3/21/24 at 10:20 a.m. revealed the laboratory received patient specimens from outside clients for Pharmacogenomics testing. 2. A review of the laboratory's records revealed the laboratory failed to have documentation of providing written instructions to its clients that included instructions for labeling, transportation, and acceptability/rejection criteria of specimens. 3. In an interview on 3/21/24 at 9:30 a.m. in the office, after review of the records, the laboratory's CEO confirmed the above findings.</p>