

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2278233	(X3) Date Survey Completed 04/30/2024
Name of Provider or Supplier Genome-Based Diagnostics	Street Address, City, State 6064 Corte Del Cedro, Ste B, Carlsbad, CA	
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of laboratory written test procedures, review of five (5) randomly chosen patients results, and interview with the laboratory's director (LD) and testing personnel (TP); it was determined that the laboratory failed to have current written procedures for all tests performed in the laboratory. The findings included: 1. On the day of the survey on April 30, 2024, at approximately 11:45 a.m. the laboratory failed to provide written procedures approved and dated by the laboratory director for all tests performed in the laboratory. 2. For five (5) out of five (5) randomly chosen patient's samples test results reviewed covering period from 1/31/204 to 4/25/2024 no written test procedures were available to reflect procedures followed by the TP for tests performed and reported. 3. The LD and TP confirmed on April 30, 2024, at approximately 12:00 p.m. that the laboratory did not have written procedures available for all tests performed in the laboratory.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p>

This STANDARD is not met as evidenced by:
Based on the surveyor's review of policies and procedures, observation during the tour of the facility, and interview with the laboratory director (LD) and testing personnel (TP); it was determined that the laboratory lacked a policy and failed to perform and document maintenance and calibration as defined by the manufacturer and with at least the frequency specified by the manufacturer for the laboratory's small equipment. The findings included: 1. The laboratory lacked a policy and procedure for the annual maintenance and calibration, according to manufacturer's requirements, to be performed on small equipment used in the laboratory (ex: vortex mixer, micro-centrifuge, and hot baths). 2. The LD and TP confirmed on April 30, 2024, at approximately 3:00 p.m. that the laboratory did not have a policy and procedure for maintenance and calibration of small equipment and failed to follow the manufacturer's instructions on preventive maintenance and calibration of small equipment such as vortexes, mixers, micro-centrifuges, and hot baths. 3. According to the test volume declared by the laboratory on 4/30/2024, the laboratory performs approximately 10,000 tests annually.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:
Based on review of patient test results records, laboratory's policy and procedure manual, and interviews with the laboratory director (LD) and testing personnel (TP); it was determined that the laboratory failed to establish written policies and procedures for turn-around-times of each test results as part of an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the post analytic systems. The findings included: 1. The laboratory did not have a written policy or procedure for turn-around-times (TAT) for each of the tests performed in the laboratory. 2. For two (2) out of five (5) randomly chosen patients test results reviewed, the time of sample collection, time the sample was received at the laboratory, and time tests were performed and reported exceeded the general TAT verbally proposed by the LD. 3. The LD and TP affirmed on April 30, 2024, at approximately 12:30 p.m. that the laboratory did not have a written policy or procedure for monitoring turn-around-times for each test performed in the laboratory. 4. Based on the laboratory's annual test declaration submitted and signed by the laboratory director on April 30, 2024; the estimated laboratory test volume was 10,000 tests for which there was no-turn-around time established policy to monitor timely tests' results reporting during the postanalytic phase of testing.

D6082

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(1)

The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.

This STANDARD is not met as evidenced by:

Based on the surveyor review of the laboratory's policies and procedures, lack of standard operating procedures, review of five (5) randomly chosen patient tests records, observation during the laboratory tour, and interviews with the laboratory director and testing personnel on April 30, 2024; the laboratory director is cited herein due to failure to ensure that several aspects of the preanalytic, analytic, and postanalytic phases of the laboratory testing were monitored. See D5401, D5429, and D5891.