

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2066797	(X3) Date Survey Completed 04/22/2021
Name of Provider or Supplier Igenomix Usa Inc	Street Address, City, State 5201 Waterford District Drive Suite 100, Miami, FL	
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 survey was completed on 4/21/2021 to 4/22/2021 at IGENOMIX USA LLC. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following Condition was not met: 5300-Preanalytic Systems
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have the attestation signed by testing person (TP) and laboratory director (LD) failed to sign and date the review of the results of 1 event for COVID-19 Molecular test during 2020. Findings include: -Review of the College of American Pathologists (CAP) proficiency testing records revealed that for 2nd event of 2020, the TP did not sign the attestation for COVID-19 Molecular (COV2-B) and the LD failed to sign and date the review of the event of reference. During an interview on 04/21/2021 at 10:30 am, the laboratory manager confirmed that the laboratory failed to have a signed attestation by the TP for the event of reference and the LD failed to review, date and sign these results.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p>

This STANDARD is not met as evidenced by:
 Based on record review and staff interview, the laboratory failed to ensure accuracy verification twice a year for Endometrial Receptivity Analysis (ERA), Product of Conception (POC) tests for 2 out of 2 years reviewed (2019, 2020). Findings include:
 - Review of ERA proficiency testing records, revealed that the laboratory performs the accuracy verification with an internal study. Record review for 2019 and 2020, revealed that the laboratory performed 1 accuracy verification per year for this test. - Review of POC proficiency testing records, revealed that for this test the laboratory participates in the Genomics Quality Assessment (GENQAS) proficiency testing program. This program had 1 event only for 2020, the laboratory failed to perform an internal study to complete accuracy verification requirement twice a year during 2020. -During an interview on 04/21/21 at 10:30 a.m., the laboratory manager confirmed that the laboratory failed to perform accuracy verification twice per year, for the methods listed above in the years of reference.

D5300

PREANALYTIC SYSTEMS
 CFR(s): 493.1240

Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493.1249 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:
 The laboratory failed to follow the Centers for Disease Control (CDC) guidelines for COVID-19 specimen transportation and storage since May 5th , 2020. (See 5311)

D5311

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL
 CFR(s): 493.1242(a)

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:
 Based on record review and interview, the laboratory failed to follow the Centers for Disease Control (CDC) guidelines for COVID-19 specimen transportation and storage since May 5th, 2020. Finding Included: Review of TaqPath COVID-19 Combo Kit manual stated Patient samples must be collected and stored according to appropriate laboratory guidelines, according to CDC guidelines. Review CDC Interim Guidelines for Collecting and Handling of Clinical Specimens for COVID-19 Testing revealed that the temperature to store respiratory specimens should be at 2-8C for up to 72 hours after collection. If a delay in testing or shipping is expected, specimens should be stored at -70C or below. Review of PCR COVID-19 specimen transportation and storage laboratory policy stated to send samples at room temperature within 24 hours

of sample collection. In event the sample cannot be sent within 24 hours, the samples must be cooled (between 2 and 8 degrees Celsius (C)) and sent to lab before 48 hours. This policy failed to follow CDC guidelines. Review of COVID-19 Patients Report revealed : 1. Patient 51977.1 COVID-19 sample was collected on 5/18/2020 and received by the lab 5/19/2020. 2. Patient 50406.1 COVID-19 sample was collected on 5/26/2020 and received by the lab 5/27/2020. Review of Test Menu revealed 2,500 patients were tested for COVID-19. An interview on 4/22/2021 at 12:42 pm, the vice president revealed that COVID-19 PCR testing had started in May 2020. An interview on 4/22/2021 at 2:26 pm , the vice president confirmed COVID-19 specimen were received at room temperature.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

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.

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory failed to produce documentation of primary maintenance for the Nano Drop 2000/2000c from January 2020 to April 22, 2021. Findings Include: Review of Nano Drop 2000/2000c stated the primary requirement for the Nano Drop 2000/2000c is keeping the measurement pedestal surfaces clean. Upon completion of each sample measurement, wipe sample from upper and lower pedestals with clean lint free wipe to sample carryover and avoid residue buildup. Review of Nano Drop maintenance revealed no documentation of keeping pedestal surfaces surface clean from January 2020 to April 22, 2021. During interview on 4/22/2021 at 2:46pm, the laboratory manager revealed maintenance was not documented for the nano drop from January 2020 to April 22, 2021.