| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 10D0998082 | 03/11/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Neogenomics Laboratories Inc | 12701 Commonwealth Dr Ste 9, Fort Myers, 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** | An unannounced complaint survey for #2021002248 was conducted from 3/4/21 through 3/11/21 at Neogenomics Laboratories, Inc., a clinical laboratory in Fort Myers, Florida. Complaint #2021002248 was substantiated at F2000 and F2013. Neogenomics Laboratories, Inc. is not in compliance with Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements. The following is a description of the noncompliance. |
| **D2000** | ENROLLMENT AND TESTING OF SAMPLES<br>CFR(s): 493.801<br><br>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of College of American Pathologists (CAP) proficiency testing and interview with the Site Quality Manager and Site Director, the laboratory (Lab A) referred the proficiency testing to Lab B (a sister lab that has their own CLIA Certificate of Compliance) in the second testing event in 2019 in Cytogenetics and referred the proficiency testing to Lab C (another sister lab that has their own CLIA Certificate of Compliance) in the first testing event in 2020 in the Cytogenetics (See D2013). |
| **D2013** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(4) |

The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.

This STANDARD is not met as evidenced by:
Based on review of College of American Pathologists (CAP) Proficiency Testing (PT) and interview with the Site Quality Manager and Site Director, the laboratory (Lab A) referred the proficiency testing to Lab B (a sister lab that has their own Clinical Laboratory Improvement Amendments (CLIA) Certificate of Compliance) in the second testing event in 2019 in Cytogenetics and referred the proficiency testing to Lab C (another sister lab that has their own CLIA Certificate of Compliance) in the first testing event in 2020 in the Cytogenetics. Findings Included: Review of CAP instructions on page 2 of the Cytogenetics portion revealed that "If referral for testing is routinely performed for patient specimens, the practice cannot be followed for PT specimens. Referral is movement of the specimen from a laboratory with a CLIA identification number. Laboratories must ensure that personnel do not share results or refer PT specimens for any reflex or testing outside their CLIA identification number." Review of the laboratories proficiency testing policy revealed under section 6.2.3.1 states "Proficiency testing specimens are not referred to other laboratories and are not accepted from other laboratories for analysis. This prohibition takes precedence over the requirement that proficiency testing specimens be handled in the same manner as patient specimens." Under section 6.2.3.2 it states that "Laboratories that perform testing using a distributive testing model where portions of the process are performed at another laboratory with a different CAP/CLIA number must not participate in formal PT, as this is considered PT referral by CMS and is Strictly prohibited." Review of CAP proficiency testing CY-A 2020 for Cytogenetics revealed 6 proficiency testing specimens. On each of the reports it states that the technical component processing and analysis of this test was completed at Lab A and the professional component was completed at Lab C. Review of CAP proficiency testing CY-B 2019 for Cytogenetics revealed 6 proficiency testing specimens. On each of the reports it states that the technical component processing and analysis of this test was completed at Lab A and the professional component was completed at Lab B. Interview on 3/4/21 at 1:30 p.m., the Site Quality Manager and the Site Director revealed that the reports were accurate and, the digital images were read out of the 2 sister laboratories. They confirmed that the laboratory had implemented a corrective action and new policy on August 18, 2020 to prevent proficiency images being read at other CLIA certified laboratories.