

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2031805	(X3) Date Survey Completed 06/28/2021
Name of Provider or Supplier Neogenomics Laboratories Inc	Street Address, City, State 13005 North Telecom Parkway Suite 104, Temple Terrace, 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 announced CLIA recertification survey was conducted at Neogenomics Laboratories Inc. on 06/28/2021. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: D6168 - 42 C.F.R. 493.1487: Laboratories performing high complexity testing; testing personnel
D6168	<p>TESTING PERSONNEL CFR(s): 493.1487</p> <p>The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on personnel record review, review of licensure requirements, review of patient testing logs, review of job descriptions, and interview with the General Supervisor, the laboratory failed to ensure eight of 35 Testing Personnel held a Florida laboratory license prior to performing high complexity laboratory testing. Refer to D6170</p>
D6170	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(a)</p> <p>Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.</p> <p>This STANDARD is not met as evidenced by: Based on personnel record review, review of licensure requirements, review of patient testing logs, review of job descriptions, and interview with the General Supervisor,</p>

the laboratory failed to ensure that eight (#M, #N, #O, #P, #Q, #R, #T, #U) out of 35 (#C - #Z, #AA -#LL) Testing Personal (TP) that performed high complexity, fluorescence in situ hybridization (FISH), testing had a license issued by the State of Florida as required. Findings included: Record review of employee job qualification records revealed 8 TP (#M, #N, #O, #P, #Q, #R, #T and #U) performed the pre-review of FISH tests and did not possess a Florida Clinical Laboratory Technologist license as required. TP #M, #O, and #P were hired on 4/12/21 and resided in Texas. TP #N was hired on 4/12/21 and resided in Georgia. TP #Q was hired on 5/10/21 and resided in Texas. TP #R was hired on 5/10/21 and resided in Georgia. TP #T was hired on 5/10/21 and resided in North Carolina. TP #U was hired on 5/10/21 and resided in Colorado. Record review of FISH patient archived logs revealed that TP #P had reviewed 49 cases. Review of Florida Chapter 483.813 Clinical laboratory personnel license revealed a person may not conduct a clinical laboratory examination or report the results of such examination unless such person is licensed under this part to perform such procedures. Record review of the undated Clinical Laboratory Technologist Job Description revealed "Certificate Compliance Requirements" for Florida included a "current state license to perform laboratory testing = Clinical Laboratory Technologist." Interview on 06/28/21 at 2:35 PM with the General Supervisor for the FISH testing revealed the company was basing personnel licenses on the state in which the testing personnel lived in and not the state in which the laboratory was located in.