Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D1012076	10/30/2023
Name of Provider or Supplier	**Street Address, City, State**	
Ophthalmic Genomics Laboratory (Ogl)	10 Center Dr Bldg 10 Rm 10n109, Bethesda, MD	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of laboratory personnel competency assessment records and an interview with the Technical Supervisor #3 (TS#3), the laboratory failed to establish written policies and procedures to assess Technical Supervisors (TS) and General Supervisors (GS) for competency in 2021 and 2022. Findings Included: 1. The personnel form CMS-209 filled out by the laboratory at the time of the survey listed 3 TS and 2 GS for the laboratory. 2. Review of the General Guidance on Personnel Training and Competency Test and Proficiency Test, Section 4. Procedure for Competency Test, revealed, that the laboratory did not establish a TS and GS competency assessment policy. 3. Interviews with TS#3 on 10/30/2023 at 11:45 am confirmed they did not establish a written policy to assess TS and GS for competency.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by:

	Based on a review of laboratory records and an interview with the technical supervisor (TS) #3, the laboratory failed to perform comparison studies every 6 months for 5 out of 5 Cyclers used for Sanger Sequencing tests. Findings Included: 1. On October 30, 2023, the laboratory could not provide comparison studies performed every 6 months for 5 out of 5 Cyclers listed below: - Bio-Rad C1000 - Applied Biosystems MiniAmp A37028 X2 - 9700 Dual PCR Cycler, Applied Biosystems - SureCycler 8800, Agilent Technologies - Eppendorf AG Model 6321 2. Interviews with the TS#3 on 10/30/2023 at 11:00 am confirmed comparison studies were not performed every 6 months to compare the Cyclers that run the same test.
D6168	TESTING PERSONNEL CFR(s): 493.1487 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. This CONDITION is not met as evidenced by: Based on a review of personnel files and an interview with the lab director (LD) and Technical Supervisor #3 (TS#3), the laboratory failed to make sure 1 of 3 testing personnel (TP) was qualified under CLIA requirements for Sanger Sequencing testing, a Laboratory Developed Test (LDT) for the subspecialty of Chemistry. (See D6171).
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical

	laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on a record review of personnel files and an interview with the lab director (LD) and Technical Supervisor #3 (TS#3), the laboratory failed to make sure that 1 of 3 testing personnel was qualified under CLIA requirements. 1. The personnel form CMS-209 filled out by the laboratory at the time of survey listed 3 testing personnel (TP) for Sanger Sequencing testing, a Laboratory Developed Test (LDT) for the subspecialty of routine chemistry. The form CMS-116 filled out by the laboratory at the time of survey listed annual test volume of 50 for the subspecialty of Chemistry. 2. The surveyor requested an official transcript for the Testing Personnel #3 (TP#3) on 10/30/2023 around 10:30 am. The laboratory could not provide documentation prior to the end of the survey of 10/30/2023 at 12:30 pm. The laboratory Technical Supervisor #3 (TS#3) emailed the official transcript of TP#3 to the surveyor on 10/31/2023 at 11:24 am. 3. Review of TP#3 educational official transcript revealed that TP#3 completed following education: a. Associate of Science in Mathematics: From the transcript for this degree, the TP#3 has completed, CHM 111 = 4 Semester hours CHM 112 = 4 Semester hours Total chemistry = 8 Semester hours b. Bachelor of Science major in Bioengineering and minor in Neuroscience: From the transcript for this degree, the TP#3 has completed, BIOL 213 = 4 Semester hours Total biology = 4 Semester hours c. TP#3 did not complete 24 credit hours of science that are required for testing personnel requirements under CLIA. 4. In a zoom call with LD and TS#3 on 11/8/23, at approximately 1:30 pm, the surveyor informed the LD and TS#3 the outcome of reviewing official transcript of TP#3 and the fact that TP#3 is not qualified to perform high complexity testing based on their education.