Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D1012076	01/15/2026
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
D0000	A Federal Surveyor from the Division of Clinical Laboratory Improvement and Quality (DCLIQ) Survey Branch conducted an announced CLIA recertification survey at the Ophthalmic Genomics Laboratory on January 15, 2026. The laboratory was surveyed under 42 CFR part 493 CLIA regulations and was found to be out of compliance with standard level CLIA requirements. The following standard level deficiencies were found.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) 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. This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) records and interview with the Technical Supervisor #3 on the Form CMS-209 (TS3), the laboratory failed to provide attestation statements and signatures by the testing personnel and Laboratory Director for five of five PT events in 2025. Findings: 1. A review of the PT records revealed there were no attestation statements with signatures of the testing personnel and the Laboratory Director included in the following PT events: 04/15/2025: Blue Cone Monochromacy Testing 12/19/2025: Blue Cone Monochromacy Testing 04/09/2025: RS1 Gene Sequencing and Deletion Testing 07/16/2025: RS1 Gene Sequencing and Deletion Testing 04/15/2025: RPGR ORF15 Sequencing and Deletion Testing 2. In an interview on 01/15/2026 at approximately 10:30 AM, the TS3 confirmed the laboratory failed to include an attestation statement with testing personnel and Laboratory Director signatures for the five of five PT events listed above from 2025.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)

	(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation during a laboratory tour, a review of instrument manufacturer's instruction manual, review of laboratory room temperature records, review of the laboratory Individualized Quality Control Plan (IQCP) and interview with the Technical Supervisor #3 on the Form CMS-109 (TS3), the laboratory failed to establish an acceptable room temperature range within the IQCP consistent with instrument manufacturer's operating requirements for three of three months from April 1, 2025 to June 30, 2025. Finds: 1. During a laboratory tour of room 10N262 on 01/15 /2026 at 10:00 AM, a Bio-Rad Automated Droplet Generator, used for specimen testing, was observed. 2. A review of the Bio-Rad Automated Droplet Generator instruction manual revealed a manufacturer's room temperature requirement for operation as 18C to 30C. 3. A random quarterly review (01/01/2025 to 06/30/2025) of room 10N262 temperature records revealed an acceptable room temperature range of 20C to 28C, established by the laboratory. 4. A review of the Ophthalmic Genomics Laboratory IQCP, Version 1, Amendment 13, page 37 revealed the following statement, "Ambient room temperature between 60F and 85F is appropriate for testing procedures." 5. In an interview on 01/15/2026 at 12:00 PM, the TS3 confirmed the laboratory failed to establish an acceptable room temperature range in the laboratory's IQCP consistent with the operating room temperature requirements by the instrument manufacturer for three of three months (April 2025 through June 2025).