Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D1037777	08/27/2019
Name of Provider or Supplier	**Street Address, City, State**	
Ocular Genomics Institute	243 Charles Street, Boston, MA	

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 initial CLIA certification survey was conducted for Molecular Lab Mass Eye and Ear Infirmary laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D5219	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2) At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on record review and staff interview with the Laboratory Director (LD), the laboratory failed to twice annually ensure the accuracy of the Genetic Eye Disease (GEDi) diagnostic test as evidenced by the following: The surveyor asked the LD on 8/27/19 for documentation of twice annual accuracy checks for the Genetic Eye Disease (GEDi) diagnostic test for 2017, 2018, and 2019. The LD could not provide documentation for accuracy checks for 2017, 2018, and 2019. The laboratory last performed accuracy checks twice in 2016 (2/10/16 and 5/27/16). The LD confirmed in an interview on 8/27/19 at 9:40 A.M. that the laboratory failed to perform twice annual accuracy checks for 2017, 2018, and 2019.
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 staff interview with the Laboratory Director (LD), the laboratory failed to establish written specimen acceptability and rejection policies and procedures for the submission of DNA and saliva samples for Genetic Eye Disease (GEDi) diagnostic testing as evidenced by the following: The surveyor conducted a record review on 8/27/19 of patient sample receipt logs for specimens received 1/2/19 through 8/27/19. The review revealed that 3 DNA samples and 12 saliva samples were received by the laboratory during this time period for testing. The surveyor conducted a record review on 8/27/19 of Genetic Eye Disease (GEDi) Diagnostic Test Information updated on 11/1/16. The review revealed under section, "Specimen and Shipment Requirements", that "Blood Specimens are the preferred specimen for testing", but lacked specimen and shipment requirements for the submission of DNA and saliva samples. The LD confirmed in an interview on 8/27/19 at 10:35 A.M. that the laboratory failed to establish written specimen acceptability and rejection policies and procedures for the submission of DNA and saliva samples for Genetic Eye Disease (GEDi) diagnostic testing.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on procedure manual review and staff interview with the Laboratory Director (LD), the LD failed to approve, sign, and date the laboratory policies and procedures as evidenced by the following: The surveyor reviewed the clinical laboratory policies and procedures manual on 8/27/19. The review revealed that the LD had not documented a review and approval of the laboratory policies and procedures manual. The LD confirmed in an interview on 8/27/19 at 11:00 A.M. that she failed to document a review and approval of the policies and procedures manual.