Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0889747	08/01/2023
Name of Provider or Supplier	**Street Address, City, State**	
Genetic Assays Inc	4711 Trousdale Drive, Suite 209, Nashville, TN	

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
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) records and staff interview, the laboratory failed to evaluate non-graded PT scores for Infectious Disease, Respiratory (IDR), SARS-CoV-2, Molecular (COV2), and Viral Load (VLS) analytes in 2022 (33 of 123 PT results) and 2023 (15 of 85 PT results). The findings include: 1. Review of the laboratory PT records revealed the following: a) 2022 IDR event C (samples 11, 12, 13, 14, 15): -Five ungraded results for Influenza A subtype. -Five ungraded results for Parainfluenza subtype. -Five ungraded results for Coronavirus Strain. b) 2023 IDR event A (samples 1, 2, 3, 4, 5): -Five ungraded results for Influenza A subtype. -Five ungraded results for Parainfluenza subtype. -Five ungraded results for Coronavirus Strain. c) 2022 COV2 event B (samples 4, 5, 6): -Two ungraded results (5 and 6) for N 1 Ct Values. -Two ungraded results (5 and 6) for N 2 Ct Values. d) 2022 COV2 event A (samples 1, 2, 3): -Two ungraded results (1 and 3) for N 1 Ct Values. -Two ungraded results (1 and 3) for N 2 Ct Values. e) 2022 VLS event B (samples 13, 14, 15, 16, 17, 18): -Two ungraded results (17 and 18) for Adenovirus, Log 10. f) 2022 VLS event C (samples 23, 24, 25, 26, 27, 28): -Two ungraded results (23 and 24) for CMV Interpretation. -Two ungraded results (25 and 26) for EBV Interpretation. -Two ungraded results (27 and 28) for CMV Interpretation. -Two ungraded results (27 and 28) for Adenovirus, Log 10. 48 of 208 PT results reviewed were ungraded and did not have documented evaluations of accuracy by the laboratory. 2. Interview with the Technical Supervisor on 8/1/2023 at 4:00 p.m. confirmed the laboratory failed to evaluate non-graded PT scores for accuracy for Infectious Disease, Respiratory (IDR), SARS-CoV-2, Molecular

	(COV2), and Viral Load (VLS) analytes in 2022 and 2023 (48 of 208 PT results reviewed).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of laboratory's Quality Assurance Program (QAP), cleaning records, and interview with the Technical Supervisor, the laboratory failed to follow the procedure for documenting biweekly and monthly cleaning of work surfaces in the Pre-PCR and Post-PCR areas in 2021, 2022, and 2023. The findings include: 1. Review of the laboratory's quality assurance program (QAP) revealed the following statements in Section II (Laboratory Policies), under "Documented Procedures": a) "The floor and other surfaces in the lab (shelves and reagent bottles) are cleaned monthly with a 10% bleach solution." b) "To reduce the amount of amplified DNA in the enviornment, work surfaces (including the floor, shelves and reagent bottles) in the post-PCR area are cleaned biweekly with 10% bleach solution" 2. Review of the laboratory's cleaning records revealed a lack of documentation for the performance of monthly laboratory cleaning and biweekly post-PCR area cleaning of work surfaces in 2021, 2022, and 2023. 3. Interview with the technical supervisor on 8/1/2023, at 4 p. m. confirmed the laboratory failed to follow their procedure for documenting biweekly and monthly cleaning of laboratory work surfaces in 2021, 2022, and 2023.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 of the laboratory, review of manufacturer's user manual, lack of documentation, and interview with the technical supervisor, the laboratory failed to monitor the ambient temperature and relative humidity in the areas where instrumentation was used for patient molecular testing in 2021, 2022, and 2023. The findings include: 1. Observation of the laboratory on 8/1/23 at 8:15 am revealed the following equipment in use for patient testing: - 1 NucIISens EasyMAG (ID: CZC0415V8K) - 2 ThermoFisher KingFisher Flex (ID: KF-L and KF-R) - 4 BioFire Diagnostics FilmArray 2.0: 2FA01006, 2FA00500, 2FA9E488, 2FA02425) - 1 Roche 480II (ID: 25161) - 1 Roche 480 (ID: 21158) - 2 Roche Lightcycler 2.0 (ID:1417194 and 1417155) - 2 Quant Studio 12K Flex (ID: 285881766 and 285881452) - 1 Quant Studio 7K Flex (ID: 278873338) 2. Review of the manufacturer's instruction for use

	manuals revealed the following operating temperature and humidity requirements: - NucIISens EasyMAG temperature range: 15 - 30 degrees (C) with relative humidity a maximum 80% - ThermoFisher KingFisher Flex temperature range: 5 - 40 degrees (C) with relative humidity a maximum 80% - BioFire FilmArray 2.0 temperature range: 15 - 30 degrees (C) with relative humidity 20 - 80% - Roche 480II temperature range: 15 - 32 degrees (C) with relative humidity 30 - 80% - Roche 480 temperature range: 15 - 32 degrees (C) with relative humidity 30 - 80% - Roche Lightcycler 2.0 temperature range: 18 - 30 degrees (C) with relative humidity 10 - 95% - Quant Studio 12K Flex temperature range: 15 - 30 degrees (C) with relative humidity 20 - 80% - Quant Studio 7K Flex temperature range: 15 - 30 degrees (C) with relative humidity 15 - 80% 3. There were no records documenting the monitoring of ambient temperature or relative humidity for surveyor review. 4. Interview with the technical supervisor on 8/1/23 at 4 pm confirmed the laboratory failed to monitor ambient temperature and relative humidity in the areas where the instruments were used for patient molecular testing in 2021, 2022, and 2023.