Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D2147777	06/20/2023
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Genetics Lab	810 Main St, Monroe, CT	

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 record review and staff interview, the laboratory failed to establish competency assessment policy and procedures to assess competency for the regulatory responsibilities for the general supervisor (GS). Findings include: 1. Record review on 06/20/2023 of the staff training and competency files revealed lack of competency assessment documentation for the regulatory position of GS. 2. Staff interview on 06 /20/2023 at 10:00 AM with the GS confirmed the above findings. The GS further commented that he/she was unaware that a GS competency assessment is a regulatory requirement. 3. The laboratory performs 2,900 tests annually in the specialties of chemistry and hematology.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on surveyor observation, record review and staff interview, the laboratory failed to document monthly maintenance and function checks for the laboratory

	equipment in the specialties of chemistry and hematology. Findings include: 1. Surveyor observation on 06/20/2023 at 11:20 AM of the laboratory revealed a QuantStudio 12K Flex Real-Time Polymerase Chain Reaction (PCR) system by Applied Biosystems. 2. Record review on 06/20/2023 of the above instrument user guide revision D revealed the following: a. The QuantStudio 12K Flex Real-Time PCR system requires regular calibration and maintenance for proper operation. b. Monthly Maintenance Task: perform a background calibration. 3. Record review on 06/20/2023 of the QuantStudio 12K Flex Real-Time PCR maintenance console revealed lack of monthly background calibration documentation. 4. Staff interview on 06/20/2023 at 11:25 AM with the general supervisor (GS) confirmed the above findings. The GS further commented that he/she was unaware of the monthly background calibration requirement and was performing background calibration on a yearly basis instead. 5. The laboratory performs 2,900 tests annually in the specialties of chemistry and hematology.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on surveyor observation, record review and staff interview, the laboratory failed to follow its policies and procedures; define proper function checks for pipettes to ensure accurate and reliable test results in the specialties of chemistry and hematology. Findings include: 1. Surveyor observation on 06/20/2023 at 11:30 AM of the chemistry and hematology laboratory area revealed four pipettes utilized in the analytical test system with lack of documentation of calibration records. 2. Record review on 06/20/2023 of the above pipettes calibration reports revealed the following: a. Thermo Scientific F1-ClipTip 0.1-2 L, serial number: SJ01600, calibration date: 10/12/2021. b. Thermo Scientific F1-ClipTip 1-10 L, serial number: SH74553, calibration date: 07/30/2021. c. Thermo Scientific F1-ClipTip 10-100 L, serial number: SH29652 calibration date: 03/25/2021. d. Thermo Scientific F1-ClipTip 100-1000 L, serial number: SH92565 calibration date: 09/20/2021. 3. Record review on 06/20/2023 of the 'Equipment IQ/OQ/PQ, Calibration, and Maintenance' standard operating procedure revealed the following: a. Equipment operators are responsible for ensuring calibrators are current prior to using any equipment. b. The general supervisor is responsible for maintaining an equipment list detailing. i. The date of calibration and/or preventative maintenance (PM) and the person who performed the calibration. ii. Due date for the next calibration and/or PM. 4. Staff interview on 06/20/2023 at 11:46 AM with the general supervisor (GS) confirmed the above findings. The GS further commented that he/she was unaware of the pipettes calibration requirements. 5. The laboratory performs 2,900 tests annually in the specialties of chemistry and hematology.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT

	CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to establish quality assessment policies and procedures to include defined turnaround times for routine testing in the specialties of chemistry and hematology. Findings include: 1. Record review on 06/20/2023 of the 'Result Reporting Policy SOP-1012_V1-1' standard operating procedure revealed the following: a. 'The laboratory will have defined turnaround time for each of its tests'. b. Lack of documentation of defined turnaround times. 2. Staff interview on 06/20/2023 at 12:30 PM with the general supervisor (GS) noted the normal laboratory turnaround time for routine test reporting is between four to six weeks and commented that it is not defined in their policies and procedures. 3. The laboratory performs 2,900 tests annually in the specialties of chemistry and hematology.