Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2085126	10/05/2022
Name of Provider or Supplier	**Street Address, City, State**	
Serenity Laboratories, Llc	1451 Northside Drive, Nw, Atlanta, GA	

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 Clinical Laboratory Improvement Amendments (CLIA) survey was completed on October 05, 2022. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on document review and interview with the staff, it was determined that the laboratory failed to document inspections of the eyewash bottles and the two (2) flush eyewash stations as required from 2020 to 2022. The Findings include: 1. The review of maintenance records revealed that the laboratory failed to document inspections of the eyewash bottles and two(2) eyewash flush stations on a weekly basis as required in 2020 to 2022. 2. Interviews with the lab manager and General Supervisor (GS) TP#6 (CMS-209) at 2:00 PM on 10/05/2022 confirmed the laboratory failed to document weekly inspections of the eyewash bottles and two (2) flush eyewash stations from 2020 to 2022.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)

	-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on laboratory tour, instruments calibration document review and staff interview, the laboratory failed to calibrate the main centrifuge in the PCR set up room at least annually as required by the manufacturer. Findings include: 1. Review of calibration data revealed the Eppendorf 5430 centrifuge was last calibrated 03/12 /2020, a twenty-two (22) months span. 2. Interviews with the laboratory manager and the General Supervisor (GS) TP #6 (CMS 209 form) on 10/05/2022 at approximately 12:00 PM in the lab and conference room confirmed the centrifuge was not calibrated annually.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on Quality Assurance (QA) documents review and staff interview, the Lab Director(LD) and General Supervisor (GS) failed to ensure that proper QA guidelines were followed including regular review of ALL maintenance logs to identify and fix problems in the laboratory as required by Clinical Laboratory Improvement Amendments (CLIA). Findings include: 1. Laboratory maintenance document review revealed the laboratory director (LD) and the General Supervisor (GS) failed to recognize that weekly documentation and review of all eyewash equipments from 2020 to 2022 were not performed. 2. Interviews with the lab manager and General Supervisor (GS) in the conference room, on 10/05/2022, at approximately 2:50 PM, confirmed there was no documentation or review of eyewash equipment from 2020 to 2022. There was no evidence of corrective action from the LD or GS to and address the QA deficiency.