Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0884890	05/08/2023
Name of Provider or Supplier	**Street Address, City, State**	
Stone Mountain Immediate Medical Care	833 North Hairston Road, Stone Mountain, 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	On June 23, 2023 an off site follow-up review was completed. The report revealed that the plan of correction was found to be acceptable. The facility is now in compliance with CLIA regulations.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on AAFP (American Association of Family Physicians) Proficiency Test (PT) document review and staff interviews, the laboratory failed to enroll in a CMS approved PT program in 2022 and 2023. Findings: 1. Review of (AAFP) Proficiency Testing (PT) documents revealed the laboratory failed to enroll in PT testing in 2022 and 2023 resulting in FAILURE to participate in 2022 and 2023 PT testing cycles . 2. An interview with the office manager and laboratory lead (TP #4 CMS 209) in the review room, at approximately 12:10 PM on 05/08/2023, confirmed no enrollment in a CMS approved PT program in 2022 and 2023.
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 the review of personnel records and competency assessment documents, it was determined that the Technical Consultant (TC) performed annual competencies in 2021. Upon her departure later that year, the laboratory director failed to perform competencies for 2022 as required. Findings; 1. Personnel documents review revealed the laboratory director, who is also acting as the Technical Consultant (TC), did not perform annual competencies for 2 out of 2 TP #s (4 and 5 CMS 209) in 2022. 2. An interview with the office manager and lab lead (TP# 4 CMS 209) in the review room on 05/08/2023 at approximately 12:15 PM confirmed no competencies were performed in 2022 by the laboratory director.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on Quality Assessment (QA) document review and staff interviews, the laboratory failed to document ALL quality assessment activities on a monthly or quarterly basis per their QA guidelines for Hematology testing as required. The Findings: 1. Laboratory QA documents review revealed the laboratory director did not review and sign monthly QA activity checklist. NO QA checklist for Proficiency Testing (PT) was available at the time of survey 05/08/2023 for the Sysmex XP-300 Hematology analyzer in 2021, 2022 and 2023. 2. Daily maintenance logs including: Room Temperature(RT), refrigerator and humidity logs were not reviewed and signed by the lab director on a consistent monthly basis. 3. An interview with the office manager and lab lead (TP# 4 CMS 209), on 05/08/2023, at approximately 12:25 PM in the review room confirmed the lack of a proper QA activities being done and documented by the laboratory director in 2021 to 2023.
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 documents review and interview with the owners, the Lab Director(LD) failed to ensure that Quality Assurance (QA) guidelines were followed to identify and

	fix problems in the laboratory in 2021 thru 2023 as required by Clinical Laboratory Improvement Amendments (CLIA). Findings: 1. Standard Operating Procedures (SOP), QA and maintenance logs (Room Temperature, Refrigerator and QC) review revealed the Lab Director, who is also the Technical Supervisor (TS), did not review or sign Quality Assurance or maintenance logs in 2021 to 2023. 2. An interview with the laboratory's office manager and lab lead (TP# 4 CMS 209 in the review room on 05/08/2023, at approximately 12:30 PM, confirmed the LD failed to ensure proper oversight of the laboratory to solve problems as they occurred in 2021 thru 2023.