Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0884890	03/16/2021
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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on March 16, 2021. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on Proficiency Testing (PT) documents review and an interview with the Technical Consultant(TC), the laboratory failed to document corrective action for unsuccessful American Academy of Family Physicians (AAFP) proficiency test (PT) results as required by Clinical Laboratory Improvement Amendments. Findings include: 1. Review of (AAFP) PT documents revealed the laboratory failed to document corrective action for failed SYX-9 PT results of AAFP - 2020-B Event. 2. An interview with the (TC) and laboratory supervisor on 03/16/2021, in the break room at approximately 12:45 p.m., confirmed that there was no corrective action performed and documented for the above failed (AAFP) PT results.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236.

	This STANDARD is not met as evidenced by: Based on laboratory records review and interview with the technical consultant(TC), the laboratory failed to establish a written quality assessment plan (QA) to monitor, assess, and correct problems in the general laboratory. The laboratory did not have a written quality assessment policy that encompasses all of the laboratory's technical and non-technical functions. 1. The laboratory failed to have a QA to assess specimen identification and integrity, specimen identification, complaint investigations, communications with providers, personal competency, and proficiency testing performance. 2. The laboratory does not have a written QA policy, but a QA checklist was present for 2020, at the time of survey. 3. An interview with the TC on March 16, 2021, at 12:45 PM in the breakroom, confirmed that the laboratory did not have a written and established QA policy for the laboratory.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on the laboratory tour and staff interview, the laboratory failed to have professional maintenance on the centrifuge as required. Findings include: 1. Observation during the laboratory tour revealed that the Drucker Diagnostics centrifuge was last calibrated April 2018. 2. An interview with testing personnel #1 (CMS 209 form) on March 16, 2021 in the breakroom at approximately 10:20 AM, confirmed the lack of the aforementioned professional maintenance on the centrifuge.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on patient reports review for 2019/2020, and interviews with the Technical Consultant (TC) and laboratory supervisor, the laboratory failed to provide the units of measure and reference ranges for results from the Sysmex XP 300 hematology analyzer. Findings: 1. Review of patient reports for 2019 and 2020 revealed reports did not have the units of measure and reference ranges for each analyte of the Complete Blood Count (CBC) from the Sysmex XP 300 Hematology Analyzer. 2. Interviews with the TC and laboratory supervisor on 03/16/2021 at approximately 12: 30 pm in the break room confirmed that the units of measure and the reference ranges for each analyte were not on the reports pulled from 2019 and 2020 from the Sysmex XP 300 Hematology Analyzer.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on laboratory record review and interview with the technical consultant(TC), the laboratory director(LD) failed to perform and document annual competencies. Findings include: 1. Document review of the competency assessment revealed that the LD did not perform and document competency for the TC in 2021. 2. An interview with TC on March 16, 2021 at approximately 12:20 PM in the breakroom, confirmed the lack of the aforementioned document for the competency.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the procedure manual, personnel records, and an interview with the technical consultant, revealed that the laboratory did not have a competency assessment policy meeting the Clinical Laboratory Improvement Amendment (CLIA) six standards for the testing personnel specific to the specialty of Hematology. Findings include: 1. Testing Personnel (TP) record review revealed that competency assessment was performed in 2019 and 2020; however, the assessment did not contain the six CLIA criteria for personnel competency assessments. 2. An interview with the technical consultant, on March 16, 2021, at approximately 12:30 PM, in the break room confirmed that the laboratory competency assessment policy does not meet the CLIA competency six standard criteria.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's maintenance, Quality Assurance(QA) records and an interview with the (TC) and laboratory supervisor, the laboratory failed to ensure that Monthly (QA) reports and maintenance logs were reviewed and signed in 2019 and 2020. Findings include: 1. Maintenance and Quality Assurance report review revealed QA and maintenance logs (Temperatures, CBC QC, LJ charts, refrigerator

	and humidity logs) were not reviewed and signed on a consistent basis in 2019 and 2020 by the Technical Consultant(TC) or the laboratory director. 2. An interview with the (TC) and laboratory supervisor, on 03/16/2021, at approximately 01:00 pm, in the break room confirmed that maintenance logs and QA reports were not reviewed and signed by the (TC) or the laboratory director.