| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 11D0884890 | 01/18/2019 |
| **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 January 18, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiency was cited: |
| **D2009** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.<br><br>This STANDARD is not met as evidenced by:<br>Based on proficiency test (PT) document review and staff interview, the laboratory director (LD) failed to attest to the routine integration of PT samples into the patient workload as required. Findings include: 1. American Academy of Family Physicians (AAFP) PT document review revealed the LD did not sign the attestation statements for Hematology Events one through three (1-3) for 2017 and 2018. 2. An interview with Staff #2 (CMS 209) in Exam room #3 on 1/18/19 at approximately 1:00 p.m. confirmed the LD did not sign the aforementioned PT attestation statements. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. |

| | |
|---|---|
| | (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory policy and procedure manual (SOP) the laboratory failed to include required policies and procedures applicable to the test procedure as required. Findings include: 1. SOP review revealed the SOP did not contain a policy and procedure for the following: corrective action, record retention, and specimen retention, 2. An interview with Staff #2 (CMS 209) in Exam Room #3 on 1/18/19 at approximately 1:00 p.m. confirmed the aforementioned policies and procedures were not in the laboratory SOP at the time of survey. |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on calibration document review and staff interview, the laboratory failed to perform instrument calibrations with required frequency. Findings include: 1. Sysmex hematology instrument calibration document review revealed the laboratory failed to perform a required instrument calibration between 3/23/18 and 1/14/19. 2. An interview with Staff #2 (CMS 209) in Exam Room #3 on 1/18/19 at approximately 1: 00 p.m. confirmed the aforementioned gap in required instrument calibration. |

| | |
|---|---|
| **D6004** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(a)(b)<br><br>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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on testing personnel (TP) competency document review and staff interview, the laboratory director failed to delegate TP competencies to a qualified individual as required. Findings include: 1. TP competency document review revealed all initial, six-month, and annual competencies were performed by unqualified TP for 2017 and 2018 due to lack of educational qualifications. 2. An interview with Staff #2 (CMS 209) in Exam Room #3 on 1/18/19 at approximately 1:00 p.m. confirmed thhe aforementioned TP competencies were performed by an unqualified TP. |
| **D6018** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(iii)<br><br>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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;<br><br>This STANDARD is not met as evidenced by:<br>Based on proficiency test (PT) document review and staff interview, the laboratory director (LD) failed to review PT reports as required. Findings include: 1. American Academy of Family Physicians (AAFP) PT document review revealed the LD failed to review PT reports for all three Hematology events in 2017 and 2018. 2. An interview with Staff #2 (CMS 209) on 1/18/2019 in Exam Room #3 at approximately 1:00 p.m. confirmed the LD did not review the aforementioned PT event reports. |
| **D6029** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(11)<br><br>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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can |

| | |
|---|---|
| | perform all testing operations reliably to provide and report accurate results.<br><br>This STANDARD is not met as evidenced by:<br>Based on personnel competency document review and staff interview, the laboratory director (LD) failed to ensure all personnel have demonstrated competency for the type and complexity of the services offered as required. Findings include: 1. Personnel competency document review revealed the technical consultant (TC) did not demonstrate competency for the type and complexity of the services offered in 2017 or 2018. 2. An interview with Staff #4 (CMS 209) on 1/18/19 in Exam Room #3 at approximately 1:00 p.m. confirmed the TC did not demonstrate competency for the type and complexity of the services offered for 2017 and 2018. |