

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1001952	(X3) Date Survey Completed 08/27/2019
Name of Provider or Supplier Monroe Pediatrics	Street Address, City, State 311 Alcovy Street, Monroe, 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 August 27, 2019. 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:
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory failed to test the PT samples with the laboratory's regular patient workload by testing personnel (TP) who routinely perform the testing as required. Findings include: 1. American Academy of Family Physicians (AAFP) PT document review revealed Staff #4 (CMS 209) tested all PT samples for all three 2018 Hematology events and 2019 Hematology events 1 and 2. 2. An interview with Staff #4 (CMS 209) on 8/27/2019 in the breakroom at approximately 11:00 a.m. confirmed she performed PT samples testing for the aforementioned Hematology PT events.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p>

	<p>This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory failed to establish and follow written policies and procedures to assess employee competency. Findings include: 1. SOP review revealed the absence of the CLIA six-procedure competency policy and procedure for assessing employee competency. 2. An interview with Staff #4 (CMS 209) in the breakroom on 8/27/2019 at approximately 11:00 a.m. confirmed the SOP did not contain a competency policy and procedure.</p>
<p>D5221</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory failed to document required corrective action for unacceptable PT results. Findings include: 1. American Academy of Family Physicians (AAFP) PT document review revealed the laboratory failed to perform corrective action for a score of 80 percent for the 2018 Hematology second PT event. 2. An interview with Staff #4 (CMS 209) at approximately 10:45 a.m. on 8/27/2019 in the breakroom confirmed no corrective action was performed for the aforementioned AAFP PT event.</p>
<p>D5291</p>	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems identified in the general laboratory systems. Findings include: 1. SOP review revealed the laboratory did not establish and follow a Quality Assurance (QA) policy and procedure. 2. An interview with Staff #4 (CMS 209) in the breakroom on 8/27/2019 at approximately 11:00 a.m. confirmed the SOP did not contain a QA policy and procedure.</p>
<p>D5401</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff</p>

interview, the laboratory failed to establish procedures for all tests, assays, and examinations performed by the laboratory as required. Findings include: 1. The laboratory failed to include the following policies and procedures in the SOP: Proficiency testing Record retention 2. An interview with Staff #4 (CMS 209) in the breakroom on 8/27/2019 at approximately 10:30 a.m confirmed the aforementioned policies and procedures were not included in the SOP.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

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.

This STANDARD is not met as evidenced by:
Based on review of the laboratory policy and procedure manual (SOP) and staff Interview, the laboratory failed to establish a written policy and procedure for all phases of laboratory testing as required Findings include: 1. The laboratory failed to establish a policy and procedure for the following: Specimen collection for urine and throat laboratory testing Criteria for specimen acceptability and rejection Quality control procedures Calibration and calibration verification Panic or alert patient values Specimen storage policy Course of action if test system becomes inoperable 2. An interview with Staff #4 (CMS 209) on 8/27/2019 in the breakroom at approximately 2:30 p.m. confirmed the aforementioned policies and procedures were not included in the the SOP.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

	<p>This STANDARD is not met as evidenced by: Based on laboratory maintenance document review and staff interview revealed the laboratory failed to define criteria for monitoring temperature and humidity as required. Findings include: 1. Laboratory temperature and humidity document review revealed the lack of acceptable ranges for room temperature (RT) and humidity on the temperature/humidity logs for 2017 and 2019. 2. An interview with Staff #4 (CMS 209) in the breakroom on 8/27/2019 at approximately 11:00 a.m confirmed the lack of acceptable RT and humidity ranges on the temperature/humidity logs for the aforementioned dates.</p>
<p>D5429</p>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of hematology analyzer documents and staff interview, the laboratory failed to perform and document instrument maintenance as required. Findings include: 1. Hematology analyzer (AcT Diff) document review revealed no instrument maintenance documents were available at the time of survey for 2017 (September through December), 2018, and 2019 thus far. 2. An interview with Staff #4 (CMS 209) in the breakroom on 8/27/2019 at approximately 12:00 p.m confirmed the aforementioned documents were not available at the time of survey.</p>
<p>D5441</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality control (QC) documents and staff interview, the laboratory failed to monitor over time the accuracy and precision of their laboratory testing as required. Findings include: 1. Hematology QC document review revealed there were no Levey-Jennings charts for 2017 (September through December), 2018, and 2019 thus far. 2 An interview with Staff #4 (CMS 209) in the breakroom on 8/27/2019 at approximately 2:00 p.m. confirmed there were no Levey-Jennings charts available at the time of survey for the aforementioned dates.</p>
<p>D6029</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p>

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.

This STANDARD is not met as evidenced by:
Based on testing personnel (TP) document review and staff interview, the laboratory director (LD) failed to ensure all TP receive appropriate training for the type and complexity of the services offered and have demonstrated they can perform all testing operations reliably as required. Findings include: 1. TP competency document review revealed an initial competency was not performed for Staff #6 (CMS 209) in 2019 2. An interview with Staff #4 (CMS 209) in the breakroom on 8/27/2019 at approximately 12:00 p.m confirmed the lack of initial competency for the aforementioned TP.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(13)

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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:
Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory director (LD) failed to ensure an approved SOP was available to all personnel responsible for any aspect of the laboratory testing process as required. Findings include: 1. SOP review revealed the LD failed to approve the laboratory SOP establish an approved SOP for laboratory testing in 2017, 2018, and 2019 thus far. 2. An interview with Staff #4 (CMS 209) in the breakroom on 8/27 /2019 at approximately 2:30 p.m. confirmed the LD did not approve the SOP for the aforementioned time periods.

D6032

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(14)

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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen

processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory director (LD) failed to specify in writing the duties and responsibilities of each testing employee engaged in the performance of all phases of laboratory testing as required. Findings include: 1. SOP review revealed the absence of a duties and responsibilities policy and procedure. 2. An interview with Staff #4 (CMS 209) in the breakroom on 8/27/2019 at approximately 2:45 p.m. confirmed there was not a duties and responsibilities policy and procedure in the SOP.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
Based on testing personnel (TP) document review and staff interview, the technical consultant/laboratory director (TC/LD) failed to perform an annual competency on TP as required. Findings include: 1. TP competency document review revealed the TC /LD failed to perform annual competencies for the following TP on the CMS 209 -- Staff #4, Staff #5, Staff #7, and Staff #8 for 2017, 2018, and 2019 thus far. 2 An interview with Staff #4 (CMS 209) in the breakroom on 8/27/2019 at approximately 12:00 p.m. confirmed the lack of annual competencies for the aforementioned TP for 2017, 2018, and 2019 thus far.