Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D1001952	03/08/2022
Name of Provider or Supplier	**Street Address, City, State**	
Monroe Pediatrics	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 March 8, 2022. 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:
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 Proficiency Testing document review and staff interview, the laboratory failed to enroll Hematology in an approved proficiency testing program. The Findings include: 1. PT document review revealed that the laboratory failed to enroll into the speciality of hematology for years 2020 and 2021. 2. During an interview on March 8, 2022 at 11:10 AM with Testing Personnel#1(CMS 209), in the laboratory, confirmed that the laboratory failed to enroll into an approved PT program, in the speciality of hematology, for years 2020 and 2021.
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: A review of personnel records and staff interview confirmed that the laboratory failed to establish a written policy to assess the six CLIA required criteria for employee competency for the specialty of hematology. The findings include: 1. The laboratory failed to have a written competency policy and procedure that include the six required criteria for testing personnel for years 2020 and 2021. 2. An annual competency assessment was not performed for any of the staff for 2020 or 2021 in the specialty of hematology. 3. During an interview with the Testing Personnel#1(CMS 209) on March 8, 2022 at 12: 10 PM, confirmed that the laboratory did not have a policy to assess the required six competency criteria for the testing personnel in the laboratory.
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 surveyor review of the standard procedure manual(SOP) document records (Pre-analytic, analytic, and post analytic) and interview with the Testing Personnel (TP), the laboratory failed to establish a written quality assessment (QA) to monitor, assess, and correct problems in the general laboratory system for quality assessment. 1. The laboratory failed to have QA policy to assess patient confidentially, specimen integrity and identification, complaints, corrective actions, proficiency test performance, or personnel competency. 2. During an interview on March 8, 2022 with TP #1(CMS 209) at 12:30 PM in the breakroom, confirmed that the laboratory did not have a written and established QA policy for the laboratory.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the general laboratory standard operating procedure manual (SOP) and staff interview, the laboratory failed to establish written instructions for sending specimens to an outside reference laboratory for testing. The findings include: 1. The SOP did not include a written policy and procedure (to include collection, preservation, storage, transport, testing schedule times, or how to obtain additional assistance) for staff to follow when sending specimens to reference laboratory (Quest,

	and LabCorp). 2. During an interview on March 8, 2022 at: 11:45 AM with Testing Personnel #1(CMS 209), in the breakroom, confirmed that the laboratory did not have a written policy and procedure for staff to follow when sending specimens to reference laboratories.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: Based on the review of the laboratory policy, standard operating procedure (SOP), and staff interiew, the laboratory failed to establish procedures for all tests and examinations peformed by the laboratory. The Finding include: 1. The laboratory failed to include the following policies and procedures: Critical Values/Pain Values, Specimen Retention, and Proficiency testing. 2. During an interview on March 8, 2022 at approximately 12:00 PM with Testing Personnel#1(CMS 209), in the breakroom, confirmed the aforementioned statement.
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 all aspects of the laboratory testing process as required. Findings include: 1. SOP (Pre-analytic, analytic, and post-analytic) review revealed the LD failed to have the following procedures included in the laboratory SOP: Critical Values/Pain Values, Proficiency Testing, and Specimen Storage for 2020 and 2021. 2. During an interview with the Testing Personnel#1 (CMS-209), on March 8, 2022, at approximately 12:30 PM, in the breakroom, confirmed the LD did not have the following procedures included in the SOP: Critical Values/Pain Values, Proficiency Testing, and Specimen Storage for 2020 and 2021.
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 person engaged in the performance of the pre-analytic, analytic, and post-analytic phases of laboratory testing. Findings include: 1. SOP review revealed the LD failed to specify in writing the duties and responsibilities of each person engaged in the performance of all phases(Pre-analytic, analytic, and post-analytic) of laboratory testing. 2. During an interview on March 8, 2022 with Testing Personnel#1(CMS 209 at 12:25 PM, in the breakroom)confirmed the SOP did not contain the duties and responsibilities for all personnel engaged in the performance of clinical laboratory testing.
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 review of testing personnel(TP) documents and staff interview, the technical consultant failed to perform annual competency on all testing personnel. The Findings include: 1. Based on competency record revie, the technical consultant failed to perform competency on all testing personnel for years 2020 and 2021. 2. During an interview on March 8, 2022, at approximately 11:30 AM, with Testing Personnel#1 (CMS 209), in the breakroom, confirmed that technical consultant failed to perform competency on all testing personnel for years 2020 and 2021.