Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0976863	09/29/2022
Name of Provider or Supplier	**Street Address, City, State**	
Prime Pediatrics Pc	1610 Broadrick Drive, Dalton, 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 September 29, 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:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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 This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) profiency test (PT) records and interview with the offfice manager , the laboratory failed to rotate PT samples with all testing personnel who routinely perform the testing in the laboratory. Findings include: 1. Review of API hematology 2021 PT testing events 1, 2, 3, and 2022 testing event 1, the same staff [#6 and #7 (CMS 209)] ran all 20 specimens of the 4 PT testing events per the attestation statements available. 2. Review of API bacteriology 2021 PT testing events 1, 2, 3 the same staff [#6 and #7 (CMS 209)] ran all 15 specimens of the 3 PT testing events per the attestation statements available. 3. Interview with the practice manager in the breakroom on 09/29/22 at approximately 12:03 P.M, confirmed the aforementioned statements.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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.

	This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) profiency test (PT) records and interview with the office manager, the laboratory testing personnel (TP) and lab director failed to attest that PT samples were tested in the same manner as patient specimens. Findings include: 1. Reveiw of API PT records revealed the lab failed to have the attestation statements signed by the TP and lab director for hematology 2022 event 2; and 2022 events 1 and 2 for bacteriology. 2. Interview with the practice manager in the breakroom on 09/29/22 at approximately 12:03 P.M, confirmed the aforementioned statement.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) Proficiency Test (PT) documents and staff interview, the lab failed to test samples the same number of times that it routinely tests patient samples. Findings include: 1. Review of API corrective action documentation for 2021 event 1 stated "2 lab techs will be present and perform proficiency testing together and the lab director will verify results prior to submission". 2. Interview with the office manager on 9/29/22 at 12:03 P.M in the breakroom, confirmed that each PT sample is ran 2 times and results are compared before reporting to the PT provider.
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 American Proficiency Institute (API) proficiency testing (PT) document review and interview with the practice manager, the laboratory failed to document corrective actions for unacceptable scores received in bacteriology testing. Findings include: 1. Review of API PT result documents revealed the lab received a score of 80% for 2021 event 3 without documenting the corrective action taken for the unacceptable result (UR-13). 2. Interview with the office manager on 9/29/22 at 12:13 P.M in the breakroom, confirmed PT sample UR-13 was unacceptable and corrective actions was not documented.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)

	(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of Medonic - M calibration documents and staff interview, the laboratory failed to calibrate the Medonic - M hematology analyzer at the frequency required by the manufacturer. Findings include: 1. Review of the Medonic- M calibration records reveals the analyzer was calibrated on 11/18/20, 1/14/21, 12/14/21, and 9/21/22. The lab failed to perform calibration in July 2021 and June 2022. 2. Interview with the practice manager in the breakroom on 09/29/22 at approximately 12:15 PM, confirmed the lack of the aforementioned calibration documents.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (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. This STANDARD is not met as evidenced by: Based on quality control (QC) document review and staff interview, the lab failed to monitor over time the accuracy and precision of test performance. Findings include: 1. Review of hematology Medonic M series QC revealed the lab is not reviewing Levy-Jennings QC charts to 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. 2. Interview with the practice manager in the breakroom on 09/29/22 at approximately 12:15 PM, confirmed the lack of the aforementioned QC documents.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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 review of testing personnel (TP) documents and an interview with the practice manager, the lab director failed to ensure all personnel receive the appropriate training, prior to patient testing. Findings include: 1. Review of TP documents revealed the lack of initial training documents for staff #8 & #10 (CMS 209). 2. Interview with the practice manager in the breakroom on 09/29/22 at approximately 11:30 AM, confirmed the lack of the aforementioned initial training documents.