Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D1070744	05/08/2019
Name of Provider or Supplier	**Street Address, City, State**	
Primecare Pediatrics Pc	15a Baynard Park, Newnan, 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 May 8, 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:
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 review of Quality Assessment (QA) documents and staff interview, the lab failed to follow written policies and procedures to monitor, assess, and correct problems identified. Findings include: 1. Review of the QA binder revealed the lack of documentation for the written policies and procedures. No QA monitors followed or performed November 2017 to 2018 to date. 2. An interview with the practice manager on 5/8/19 at approximately 1 PM in the practice manager's office, confirmed the QA policies were not followed. ** This is a repeat deficiency **
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 hematology calibration documents and staff interview, the laboratory failed to calibrate the Medonic M series analyzer at least once every 6 months. Findings include: 1. Review of the calibration documents revealed the facility calibrated the Medonic M analyzer on 04/14/17 and 6/18/18 (1 year 2 month span) 2. Interview with the practice manager on 05/08/19 at approximately 12:30 PM in the office of the practice manager, confirmed the analyzer was not calibrated at 6 months. ** Repeat Deficiency **
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 (long term monitoring (Levy-Jenning charts)). Findings include: 1. Review of the hematolgy QC documents revealed no long term monitoring (Levy-Jenning charts) was available for review. 2. Interview with the practice manager on 5/8/19 at approximately 1:00 PM in the office of the practice manager, confirmed the long term monitoring (Levy-Jenning charts) was not available to review.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Based on review of the Medonic M hematology quality control (QC) records and staff interview, the lab failed to document corrective actions when QC exceeded acceptable limits. Findings include: 1. Review of the Medonic M QC records: February 2018, December 2018, and February 2019 revealed one (1) or more analytes were out of range without corrective actions documented. 2. Interview with the practice manager on 05/08/19 at approximately 2 PM in the practice manager's office, confirmed the corrective actions were not documented.
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 personnel documents and staff interview, the lab director failed to follow written policies and procedures to train and evaluate competency of testing personnel (TP). Findings include: 1. Review of personnel records revealed documentation for the training on 5 of 6 testing personnel was performed by unqualified persons. 2. Review of personnel records revealed documentation for the 6 month competency evaluation on 1 of 3 testing personnel was performed by an unqualified person. 2. An interview with the practice manager on 5/8/19 at approximately 11 AM in the practice manager's office, confirmed the training and competency documents were not completed by qualified personnel. ** Repeat Deficiency **
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on review of maintenance, quality control (QC), temperature and relative humidity (RH) logs and staff interview, the technical consultant (TC) failed to provide technical oversight of the laboratory. Findings include: 1. Review of the maintenance, quality control (QC), temperature and relative humidity (RH) logs revealed the lack of review by the TC for the period of 2018 to 2019 (to date). 2. Interview with the practice manager on 5/8/19 at approximately 2 PM in the practice manager's office, confirmed the lack of the review of maintenance, quality control (QC), temperature and relative humidity (RH) logs by the TC.