Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0242687	01/17/2023
Name of Provider or Supplier	**Street Address, City, State**	
Albemarle Pediatrics	1420 Us Highway 52 N, Suite A, Albemarle, NC	

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
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i) In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: Based on the absence of records and interview with the TC (technical consultant) 1/17 /23, the laboratory failed to retain records used to verify performance of the TriMed EMR (electronic medical records system) prior to use for reporting patient test results. Review of laboratory records revealed there were no records available to document activities performed by the laboratory to verify the performance of the TriMed EMR prior to using it for reporting patient test results. During the survey, the staff was able to provide copies of emails from TriMed which included a timeline of events for conversion from Athena EMR to TriMed EMR during November and December 2020, examples of test patients, and a notification dated 12/16/20 that "all internal and external setup and testing has been completed. ..." During interview at approximately 1:50 p.m., the TC stated she was not aware the laboratory had changed their EMR.
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's policies and procedures and interview with the TC (technical consultant) and TP (testing personnel) #2 on 1/17/23, the laboratory's procedure manual was not complete and current for the testing performed. Review of the laboratory's policies and procedures revealed: 1. The complete blood count procedure included adult reference ranges, but did not include reference ranges for pediatric patients. During interview at approximately 11:40 a.m., the TC stated that the laboratory has four different reference ranges based on patient age. 2. The EMR (electronic medical records) procedure indicated the laboratory used Athena EMR, but the laboratory currently uses TriMed EMR. 3. The procedure manual did not include a procedure for reporting SARS-CoV-2 test results to state or local public health authorities. During interview at approximately 2:15 p.m., TP #2 stated they report COVID results to the state using the website.
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 manufacturer's instructions and review of 2020, 2021, and 2022 Medonic M-Series calibration records 1/17/23, the laboratory failed to follow manufacturer's instructions for the performance of calibration procedures for 2 of 6 calibrations performed. Review of the Medonic M-Series operator's manual revealed "Section 7: Calibration ... It is recommended to calibrate the instrument every six months. ... 7.1 Preparations before calibration ... The user should be thoroughly familiar with the analyzer system and the calibration procedure before performing calibration. ... 7.2 Calibration ... Once parameters are calibrated, press [EXIT] and a screen will be displayed asking operator if a calibration report is wanted... It is recommended that calibration reports be printed and archived in case it may be needed for future reference. It is recommended to run controls after calibration to

	verify that all parameters have been calibrated correctly. ..." Review of 2020, 2021, and 2022 Medonic M-Series calibration records revealed: 1. The records for the calibration performed 7/27/20 were incomplete. The laboratory failed to maintain the post calibration report and failed to run 3 levels of quality control to verify calibration. 2. The calibration performed 3/18/22 was performed late - approximately 8 months after the previous calibration on 7/14/21.