Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D1043971	(X3) Date Survey Completed 01/25/2023
Name of Provider or Supplier Color Country Pediatrics	**Street Address, City, State** 55 East Canyon Commercial Ave, Cedar City, UT	

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
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 a review of the CBC Medonic M-series Hematology Analyzer procedure and an interview with technical consultant (TC), the laboratory failed to include panic values for Complete Blood Count (CBC) testing. The laboratory performed 7,200 CBC tests annually. Findings include: 1. Review of the procedure manual on January 25, 2023 at 2:45 PM revealed a lack of panic values for CBC testing. 2. Interview with the TC on January 25, 2023 at 2:50 PM confirmed the laboratory failed to include panic values in the procedure manual.

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. This STANDARD is not met as evidenced by: Based on record review, direct observation, and interview with the technical consultant (TC), room temperature and humidity of the laboratory was not monitored. The laboratory performs approximately 7,200 hematology tests annually on the Medonic M-series Hematology Analyzer. Findings include: 1. Record review on January 25, 2023 at 2:40 PM revealed the laboratory had no records of monitoring temperature and humidity. There was no written policy that included the monitoring of temperature and humidity in the laboratory. 2. No thermometer or hygrometer was present in the laboratory during observation on January 25, 2023 at approximately 2: 23 PM. 3. The record review of the Medonic M-series User's Manual revealed that the analyzer requires an operating environment of 18C to 32C and relative humidity of up to 80%. 4. In an interview on January 25, 2023 at approximately 2:25 PM, the TC confirmed room temperature and humidity was not monitored.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) 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. This STANDARD is not met as evidenced by: Based on record review, and interview with the technical consultant (TC), the laboratory failed to document maintenance as defined by the manufacturer for the Medonic M-series Hematology Analyzer. The laboratory performs approximately 7,200 hematology tests annually on the analyzer. 1. Record review on January 25, 2023 at 2:34 PM revealed the laboratory had no records of performing maintenance for the Medonic M-series Hematology Analyzer. 2. The record review of the Medonic M-series Users's Manual revealed there are required daily, monthly, six month, and periodic maintenance for the analyzer. 3. In an interview on January 25, 2023 at approximately 2:35 PM, the TC confirmed the laboratory did not document maintenance for the Medonic M-series Hematology Analyzer.