Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0977124	09/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
Cedar Creek Pediatric & Adolescent Medicine Pc	616 Smithview Drive, Maryville, TN	

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 observation of microscope in laboratory and an annual test volume of 5 for KOH and Wet Prep Analyis, lack of procedure for KOH and Wet Prep Analysis and interview with the Laboratory Supervisor, determined the laboratory failed to have a procedure for collection, handling, performing and reporting KOH and Wet Prep Analysis for 2017 and 2018. The findings include: 1. Observation of microscope in laboratory and an annual test volume of 5 for KOH and Wet Prep Analysis. 2. Lack of procedure for KOH and Wet Prep Analyis upon review of procedure manual. 3. Interview with Laboratory

	Supervisor at approximately 3:00 p.m. September 24, 2018 confirmed there was no procedure in place for performance and reporting of KOH and Wet Prep Analysis for the two year period. ==========
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 the lack of refrigerator temperature monitoring for storage of the Complete Blood Count (CBC) quality control (QC) materials and an interview with the Laboratory Supervisor, determined the laboratory failed to define and monitor storage temperatures for CBC control materials for 2017 and 2018. The findings include: 1. There was no documentation of storage temperatures for the CBC control materials for 2017 and 2018. 2. An interview with the laboratory supervisor at approximately 4:00 p.m. September 24, 2018 confirmed the laboratory failed to define and document storage temperatures for the CBC control materials for the two year period. ==========
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: ========== Based on observation of Hematology (QC) materials in use on day of survey September 24, 2018 and upon interview with the Laboratory Supervisor, determined the laboratory failed to document open dates and new expiration dates on QC materials. The findings include: 1. An observation of Hematology (CBC) Complete Blood Count controls in use on September 24, 2018 were not dated with the open date or 14 day open vial expiration date specified by the manufacturer. 2. An interview at approximately 12:40 p.m. September 24, 2018 with the Laboratory Supervisor confirmed there were no open dates or open vial expiration dates documented on the Hematology Control Materials observed in use on September 24, 2018. ==========
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)

	For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: ========== Based on lack of protocol and lack of maintenance and function checks for the microscope and urine centrifuge and an interview with the Laboratory Supervisor, determined the laboratory failed to establish a protocol to ensure reliable test results for microscopy testing to include KOH (Potassium Hydroxide), Wet Prep and Urine Sediment Analysis for 2017 and 2018. The findings include: 1. There was no protocol established by the laboratory defining maintenance and function checks for the microscope for performing KOH and Wet Prep Analysis and urine centrifuge for performing Urine Sediment Analysis for 2017 and 2018. 2. There was no documentation of maintenance and function checks for the microscope and urine centrifuge for 2017 and 2018. 3. An interview with the laboratory supervisor at approximately 12:40 p.m. September 24th, 2018 confirmed there was no protocol or documentation of performance for maintenance and function checks for the microscope and urine centrifuge for the two year period. ==========
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: ========== Based on lack of the 6 competency assessment criteria upon review of 3 of 3 testing personnel competency evaluations and interview with the Laboratory Supervisor, determined the Technical Consultant failed to include all 6 required competency assessment criteria for 2017 and 2018. The findings include: 1. Review of competency evaluations for 3 of 3 testing personnel revealed lack of the 6 required competency criteria for 2017 and 2018 as listed: --Observation of routine patient test performance; --Monitor the recording and reporting of test results; -- Review worksheets, quality control records, proficiency testing results, and preventive maintenance records; --Observe performance of instrument maintenance and function checks; --Assess the test performance by previously analyzed samples, internal blind samples or PT samples; and --Assess problem solving skills. 2. An interview at approximately 4:00 p.m. September 24, 2018 with the Laboratory Supervisor confirmed the 3 of 3 testing personnel competencies did not include the 6 criteria for assessing competency for the two year period. ==========