Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0705404	07/16/2024
Name of Provider or Supplier	**Street Address, City, State**	
Spring Creek Pediatrics, Inc	929 Spring Creek Rd Ste 206, Chattanooga, 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
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 a review of the laboratory's defined room temperature range, a review of the laboratory's environmental records, and staff interview, the laboratory failed to maintain room temperature within the defined ranges for 168 days of 463 days in 2023 and 2024. The findings include: 1. A review of the laboratory's defined temperature range revealed a room temperature range of 22 - 28 C (71.6 - 82.4 F). 2. A review of the laboratory's Temperature/Humidity Record log for January - December 2023 and January - June 2024 revealed that the room temperature was outside the defined temperature range for 168 of 463 days. 3. In an interview on 07/16 /2024 at 1:30 p.m., the laboratory director and nurse manager confirmed the laboratory failed to maintain room temperature in the laboratory's defined range.
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 laboratory observation, review of the manufacturer's package insert, and staff interview, the laboratory failed to label three of three complete blood count (CBC) quality control (QC) vials with opened and corrected expiration dates after opening. The findings include: 1. Observation of the laboratory on 7/16/2024 at 9:05 a. m. revealed the Beckman Coulter DxH 500 Hematology Analyzer (Serial Number BG020025) in use for patient testing and DxH 500 Series Control Lots 352416111, 362426112, and 372416113 in use for QC testing. The QC vials were not labeled with opened and corrected expiration dates. 2. A review of the manufacturer package insert revealed the controls were stable for 16 days after opening. 3. An interview with the laboratory director and nurse manager on 07/16/2024 at 1:30 p.m. confirmed the laboratory failed to label the QC vials with opened and corrected expiration dates.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) records, the laboratory's proficiency testing policy and interview with the laboratory director and the nurse manager, the laboratory director failed to ensure the laboratory's corrective action plan was followed for unacceptable proficiency testing scores for Monocytes (%) 2023- event three, 1 of 5 results. The findings include: 1. A review of the laboratory's proficiency testing records revealed an unacceptable score for Monocytes (%) for DXH-14 from PT 2023- event three. The lab director failed to document corrective action in the signed evaluation on 1/11/2024. 2. A review of the laboratory's proficiency testing policy revealed the following: "The lab director will review the results reported by the API to evaluate any unacceptable, unsatisfactory or unsuccessful proficiency testing result and identify the cause of the unacceptable results. If/when a cause is found, corrective action will be taken, documented and change implemented." 3. An interview with the laboratory director and nurse manager on 07/16/2024 at 1:30 p.m. confirmed the laboratory director failed to ensure that corrective action was documented for unacceptable results.