Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0977124	(X3) Date Survey Completed 05/05/2025
Name of Provider or Supplier Cedar Creek Pediatric & Adolescent Medicine Pc	**Street Address, City, State** 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
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) (a)Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(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 (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(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 observation of the laboratory, review of the Medonic operator's manual, Medonic calibration records, and staff interviews, the laboratory failed to ensure calibration for the Medonic Complete Blood Count (CBC) instrument every six months as recommended by the manufacturer in 2024. The findings include: 1. An observation of the laboratory on 05.05.2025 at 8:35 a.m. revealed a Medonic CBC instrument, serial #19194, used for patient testing. 2. Review of the Medonic operator's manual revealed the following statement: "Calibrate instrument every 6 months based on manufacturer's recommendations and in accordance with local regulations." 3. A review of the Medonic calibration records revealed no calibration record for August 2024. 4. An interview with the Nurse Manager on 05.05.2025 at 12:30 p.m. and a follow-up electronic message on 05.13.2025 at 2 p.m. confirmed the above survey findings.
D6063	LABORATORY TESTING PERSONNEL

	CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on observation of the laboratory, review of patient test reports, personnel qualifications, and staff interview, testing person number two (TP2) did not meet the regulatory education requirements for moderately complex testing personnel (Refer to D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS-209), lack of documentation, and staff interview, testing personnel number two (TP2) did not qualify to perform moderately complex patient testing due to a lack of documentation of the highest level of education (one of three new testing personnel since the last survey). The findings include: 1. A review of the CMS-209 form revealed TP2 listed as performing moderately complex patient testing. 2. A review of testing personnel records revealed no documentation of the highest level of education for TP2. 3. An interview with the Lab Liaison on 05.05.2025 at 12: 30 p.m., and a follow-up electronic message on 5.06.2025 at 1:51 p.m. confirmed the above survey findings.