

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0977124	(X3) Date Survey Completed 02/14/2022
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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: ===== Based on review of Proficiency Testing (PT) reports for 2020 and 2021, attestation sheets which lacked testing personnel and director signatures and upon interview with the lead testing person, determined the testing personnel and laboratory director failed to sign attestation sheets. The findings include: 1. Review of PT reports for 2020 and 2021. 2. Review of attestation sheets revealed lack of testing personnel and lab director signature for third event 2020 and first, second, and third events 2021. 3. Interview at approximately 12:30 p.m. February 14, 2022 with the lead testing person confirmed the PT attestation sheets for 2020 and 2021 lacked testing personnel and director signatures as stated. =====</p>
D5481	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: ===== Based on review of Complete Blood Count (CBC) Quality Control (QC) records for November 10, 2020, CBC QC</p>

not tested until after patient CBC testing and upon interview with the lead testing person, determined the laboratory failed to ensure CBC QC was acceptable before reporting six patient CBC results on 11.10.2020. The findings include: 1. Review of Hematology Complete Blood Count (CBC) quality control records for November 10, 2020. 2. CBC quality control documented at 7:25 p.m. with six patient CBC's documented between 12:19 p.m. and 6:24 p.m. on 11/10/2020. 3. Interview with the lead testing person at approximately 12:30 p.m. on February 14, 2022 confirmed that CBC quality control was not ran prior to six patient CBC's tested and reported on 11 /10/2020. =====

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 review of employee personnel records for 2020 and 2021 and interview with the lead testing person, the laboratory's technical consultant failed to document the six required criteria for assessing personnel competency for Testing Personnel (TP) one and two out of five. The findings include: 1) Review of employee personnel records for 2020 and 2021 did not reveal documentation of the six required criteria of competency that include: direct observation of routine patient test performance; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results and preventative maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and, assessment of problem solving skills. 2) An interview with the lead testing person on February 14, 2022 at approximately 12:30 p.m. confirmed TP one and two of five TP evaluated during 2020 and 2021 were not evaluated using the six criteria for competency required by Centers for Medicare and Medicaid (CMS).
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