

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  26D0446983	<b>(X3) Date Survey Completed</b>  01/02/2025
<b>Name of Provider or Supplier</b>  Central Ozarks Medical Center	<b>Street Address, City, State</b>  304 W Washington Ave, Richland, MO	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>(b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual on January 2, 2025, lack of corrective action documentation for 2024 and interview with testing personnel #1, the procedure manual failed to include corrective action steps for hematology controls that fail to meet acceptable criteria. Findings: 1. The procedure manual did not include written corrective action steps for controls performed on the ABX Pentra 60 CT hematology analyzer that fail to meet acceptable criteria. 2. The laboratory could not provide hematology corrective action documentation for 2024 and a mechanism for</p>

documenting corrective action for hematology controls that fail to meet acceptable criteria. 3. Interview with testing personnel #1 on January 2, 2025 at 12:15 PM confirmed, the procedure manual failed to include corrective action steps for hematology QC. Based on review of the laboratory procedure manual on January 2, 2025 and interview with testing personnel #1, the procedure manual failed to include reference intervals (normal values) for 15 of 15 hematology tests performed on the ABX Pentra 60 CT analyzer and 19 of 19 chemistry tests performed on the Pentra 400 chemistry analyzer. Findings: 1. The procedure manual did not include normal values for hematology tests performed on the ABX Pentra CT analyzer; white blood cells (WBC), neutrophils, lymphocytes, monocytes, eosinophils, basophils, red blood cells (RBC) hemoglobin, hematocrit, MCV, MCH, MCHC, RDW, platelets and MPV. The procedure manual did not include normal values for chemistry tests performed on the Pentra 400 chemistry analyzer; glucose, BUN, sodium, potassium, chloride, CO<sub>2</sub>, AST, ALT, alkaline phos, total bilirubin, total protein, albumin, calcium, direct bilirubin, creatinine, LDL, total cholesterol, HDL and triglycerides. The laboratory could not provide pertinent approved hematology and chemistry normal values. 2. Interview with testing personnel #1 on January 2, 2025 at 12:15 PM confirmed, the procedure manual failed to include hematology and chemistry normal values.