

<p><b>Statement of Deficiencies</b></p>	<p><b>(X1) Provider/Supplier/CLIA Identification Number</b></p> <p>37D2020809</p>	<p><b>(X3) Date Survey Completed</b></p> <p>06/12/2024</p>
<p><b>Name of Provider or Supplier</b></p> <p>Cpn West Clinic</p>	<p><b>Street Address, City, State</b></p> <p>781 Grand Casino Blvd, Suite 134 Lab, Shawnee, OK</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p><b>(X4) ID Prefix Tag</b></p>	<p><b>Summary Statement of Deficiencies</b></p>
<p><b>D0000</b></p>	<p>The recertification survey was performed on 06/11,12/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the technical consultant and testing person #5 at the conclusion of the survey.</p>
<p><b>D5421</b></p>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to utilize the demonstrated reportable range for creatinine testing using the Nova Stat/Sensor creatinine/eGFR meter system put into use on 7/11/2023. Findings include: (1) On 06/12/2024 at 11:15 am, the technical consultant stated the laboratory began testing on the Nova Stat/Sensor for creatinine testing 07/11/2023; (2) A review of the performance specification records for the analyzer identified the laboratory had demonstrated the following reportable range: (a) Creatinine - 0.99 - 10.1 mg/Dl (3) Interview with the technical consultant 06/12/2024 at 11:15 am confirmed the laboratory was using the following manufacturer's reportable ranges instead of the ranges that had been demonstrated by the laboratory: (a) Creatinine - 0.3 - 12.0 mg/Dl</p>