

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  37D0906154	<b>(X3) Date Survey Completed</b>  08/26/2021
<b>Name of Provider or Supplier</b>  Surgical Hospital Of Oklahoma, Llc	<b>Street Address, City, State</b>  100 Se 59th Street, Oklahoma City, OK	
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>D0000</b>	The initial survey was performed on 08/26/2021. The laboratory was found in compliance with a standard-level deficiency cited. The findings were reviewed with the administrator/chief clinical officer, technical consultant, and paid consultant during an exit conference performed at the conclusion of the survey.
<b>D5421</b>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE 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 paid consultant, the laboratory failed to ensure the reportable ranges were utilized for a new test method. Findings include: (1) On 08/26/2021 at 11:00 am, the paid consultant stated to the surveyor the laboratory began performing Hemoglobin, Sodium, and Chloride testing using the Radiometer ABP90 Flex Plus analyzer on 04/22/2020; (2) The surveyor reviewed the performance specification records for the new test system and identified the laboratory had demonstrated the following reportable ranges: (a) Hemoglobin - 4.9-23.3 g/dl (b) Sodium - 79-177 mmol/L (c) Chloride - 46-120 mmol/L (3) The surveyor then requested documentation to show the reportable ranges that were being utilized by the laboratory. The laboratory was using the following manufacturer's reportable ranges instead of the ranges that had been demonstrated by the laboratory: (a) Hemoglobin - 4.5-24.0 g/dl (b) Sodium - 116-180 mmol/L (c) Chloride - 86-125 mmol/L (4) The surveyor reviewed the findings with the paid consultant who stated</p>

on 08/26/2021 at 11:40 am, the laboratory was not using the reportable ranges that had been demonstrated by the laboratory as shown above.