

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  26D2240331	<b>(X3) Date Survey Completed</b>  03/30/2022
<b>Name of Provider or Supplier</b>  Modern Vascular Of St Louis Llc	<b>Street Address, City, State</b>  641 N New Ballas Rd, Creve Coeur, 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>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 review of the performance verification procedures for the Abbott i-stat analyzer and interview with testing personnel (TP) #1, the laboratory failed to demonstrate performance specifications prior to reporting patient test results. Findings: 1. Review of the performance specifications for the Abbott i-stat analyzer showed the laboratory failed to demonstrate accuracy, precision, reportable range and failed to verify that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population for the analytes: sodium, potassium, chloride, ionized calcium, glucose, blood urea nitrogen, total CO2, creatinine, hematocrit, and hemoglobin prior to the beginning of patient testing in January 2022. 2. Review of patient results from January 2022 to date March 23, 2022 showed 50 patient results were reported. 3. Interview with TP #1 on March 23, 2022 at 11:00 AM confirmed the laboratory failed to demonstrate performance specifications prior to reporting patient test results.</p>