

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D2111932	(X3) Date Survey Completed 02/25/2020
Name of Provider or Supplier Center For Advanced Medicine South	Street Address, City, State 5201 Midamerica Plaza Suite 2300, Saint Louis, MO	
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
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.</p> <p>This STANDARD is not met as evidenced by: Review of 2019 calibration records for the Gem 4000 blood gas analyzer for pH, pCO2, pO2 and interview with the testing personnel (TP), the laboratory failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value and a maximum value near the upper limit to verify the laboratory's reportable range. Findings: 1. No 2019 calibration records for the Gem 4000 blood gas analyzer were available for pH, pCO2,</p>

pO₂. 2. Interview with the TP confirmed the laboratory failed to include a minimal, mid-point, and maximum calibrator in the calibration verification procedure for pH, pCO₂, pO₂ at least once every six months.