

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  26D2111932	<b>(X3) Date Survey Completed</b>  03/28/2018
<b>Name of Provider or Supplier</b>  Center For Advanced Medicine South	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2000</b>	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of patient reports, proficiency testing records revealed and interview with the laboratory director on March 28, 2018 at 11:00 PM confirmed, the laboratory failed to enroll in proficiency testing during 2016, 2017 and to date March 28, 2018 for the analyte of total hemoglobin for blood gas testing.</p>
<b>D2003</b>	<p>ENROLLMENT CFR(s): 493.801(a)(2)(ii)</p> <p>For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1)</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency records for 2016, 2017 and to date March 28, 2018, review of patient reports and interview with the laboratory director, the laboratory failed to establish a means to verify the accuracy of four of four non-regulated</p>

analytes for arterial blood gas testing twice a year. Findings: 1. Review of proficiency records for the third event of 2016, all three events for 2017, and to date March 28, 2018, revealed the laboratory failed to enroll to prove accuracy on the non-regulated analytes of oxyhemoglobin, methemoglobin, carboxyhemoglobin and deoxyhemoglobin. 2. Review of the patient test report showed results for oxyhemoglobin, methemoglobin, carboxyhemoglobin, and deoxyhemoglobin. 3. Interview with the laboratory director on March 28, 2018 at 11:00 AM confirmed the laboratory resulted four of four non-regulated analytes on the patient report and failed to verify the accuracy of the non-regulated analytes of methemoglobin, oxyhemoglobin, deoxyhemoglobin, and carboxyhemoglobin for blood gas testing twice annually for 2016 and 2017.