

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D2111932	(X3) Date Survey Completed 06/21/2019
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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on review of 2018, 2019 routine chemistry proficiency testing (PT) results reported to the CLIA database by the PT provider and phone interview with the testing personnel, the laboratory failed to participate in PT. See D-tag 2089, failure to participate in two consecutive PT challenges.</p>
D2089	<p>ROUTINE CHEMISTRY CFR(s): 493.841(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a</p>

score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:

Based on review of proficiency test records for the third event of 2018 and the first event of 2019 and interview with testing personnel, the laboratory failed to participate in chemistry proficiency testing for blood gas analysis, resulting in unsatisfactory performance with a score of zero for the testing events. Findings: 1. Review of the third event of 2018 for routine chemistry proficiency test results showed a score of zero percent for pH, pO₂, pCO₂. 2. Review of the first event of 2019 for routine chemistry proficiency test results showed a score of zero percent for pH, pO₂, pCO₂. 3. Interview with the testing personnel on June 21, 2019 at 12:00 PM confirmed the laboratory failed to participate in the third event of 2018 and first event of 2019 for arterial blood gas testing and scored an unsatisfactory performance of zero percent.