

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D2111932	(X3) Date Survey Completed 02/19/2020
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
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 and 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 successfully participate in PT. See D-tags 2096 and 2097 failure to successfully participate in three of four consecutive PT challenges.</p>
D2096	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p>

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on review of chemistry proficiency testing (PT) results for 2018, 2019 and phone interview with the testing personnel, the laboratory failed to achieve satisfactory performance for the analytes pH, pCO₂, pO₂ in three of four PT events. Findings: 1. Review of the chemistry PT results for the third event of 2018 revealed the laboratory obtained an unsatisfactory score of 0 percent for the analytes, pH, pCO₂, pO₂. 2. Review of the chemistry PT results for the first event of 2019 revealed the laboratory obtained an unsatisfactory score of 0 percent for the analytes, pH, pCO₂, pO₂. 3. Review of the chemistry PT results for the third event of 2019 revealed the laboratory obtained an unsatisfactory score of 0 percent for the analytes, pH pCO₂, pO₂. 4. Phone interview with the testing personnel on February 19, 2020 at 1:30 PM confirmed the laboratory failed to achieve satisfactory performance for pH, pCO₂, pO₂ testing in three of four events for 2018 and 2019.

D2097

ROUTINE CHEMISTRY

CFR(s): 493.841(g)

Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on review of chemistry proficiency testing (PT) results for 2018, 2019 and phone interview with the testing personnel, the laboratory failed to achieve satisfactory performance for the specialty of routine chemistry in three of four PT events. Findings: 1. Review of the chemistry PT results for the third event of 2018 revealed the laboratory obtained an unsatisfactory score of 0 percent for routine chemistry. 2. Review of the chemistry PT results for the first event of 2019 revealed the laboratory obtained an unsatisfactory score of 0 percent for routine chemistry. 3. Review of the chemistry PT results for the third event of 2019 revealed the laboratory obtained an unsatisfactory score of 0 percent for routine chemistry. 4. Phone interview with the testing personnel on February 19, 2020 at 1:30 PM confirmed the laboratory failed to achieve an overall satisfactory performance for routine chemistry in three of four events for 2018 and 2019.