

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0405602	(X3) Date Survey Completed 05/03/2019
Name of Provider or Supplier Olivia Hospital & Clinic	Street Address, City, State 100 Healthy Way, Olivia, MN	
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 a review of Center for Medicare and Medicaid Services (CMS) reports and American Proficiency Institute (API) proficiency testing reports, the laboratory failed to successfully participate in proficiency testing for pCO2* testing, under the specialty of Chemistry. Findings are as follows: D2087 - the laboratory failed to obtain a PT score of at least 80 percent for pCO2 testing. D2093 - the laboratory failed to submit PT results prior to the submission deadline. D2096 - the laboratory failed to achieve satisfactory analyte PT performance for pCO2 testing in two out of three consecutive events. *Note pCO2 - Partial pressure of Carbon Dioxide .</p>

<p>D2087</p>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: . Based on a review of proficiency testing (PT) reports from the American Proficiency Institute (API), the laboratory failed to obtain a PT score for pCO₂ testing of at least 80 percent which resulted in unsatisfactory performance for the analyte. Unsatisfactory PT performance of pCO₂ testing was obtained in the following events: - 2018 Chemistry / Core / 2nd event: 40% .</p>
<p>D2093</p>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(d)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: . Based on a review of proficiency testing (PT) reports from the American Proficiency Institute (API), the laboratory failed to submit Chemistry PT results to API prior to the submission deadline. Findings are as follows: The laboratory failed to submit PT results for all analytes, including pCO₂, for the 2019 Chemistry / Core / 1st event. Failure to participate in the testing event resulted in unsatisfactory performance for pCO₂. .</p>
<p>D2096</p>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p> <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.</p> <p>This STANDARD is not met as evidenced by: . Based on a review of proficiency testing (PT) reports from the American Proficiency Institute (API) provider, the laboratory failed to achieve successful performance for pCO₂ testing in two out of three consecutive PT events. Findings are as follows: The laboratory failed pCO₂ testing in two out of three consecutive PT events. Two out of three consecutive PT failures for the same analyte constitutes unsuccessful performance. PT reports from API listed the following unsatisfactory pO₂ scores. - 2018 Chemistry / Core / 2nd event: 40% - 2019 Chemistry / Core / 1st event: 0%</p>