

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0405602	(X3) Date Survey Completed 05/21/2019
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 reports and proficiency testing reports from the American Proficiency Institute (API) proficiency testing (PT) provider, the laboratory failed to successfully participate in PT for the following analytes under the specialty of Hematology. - Cell Identification or White Blood Cell Differential - Erythrocyte Count - Hematocrit - Hemoglobin - Leukocyte Count - Platelet Count - Partial Thromboplastin Time - Prothrombin Time Findings are as follows: 1. The laboratory failed to submit Hematology PT results to API prior to the submission deadline. See D2127 2. The laboratory failed to achieve successful performance for Hematology testing. See D2130 3. The laboratory failed to achieve</p>

	<p>successful performance for Hematology testing in two consecutive events. See D2131 .</p>
<p>D2127</p>	<p>HEMATOLOGY CFR(s): 493.851(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 participate in the 3rd Hematology/Coagulation testing event in 2018 and 1st Hematology/Coagulation testing event in 2019, which resulted in a score of 0 for all analytes on each event. Findings are as follows: 1. Review of PT results from API revealed that the laboratory failed to participate in the 3rd Hematology/Coagulation testing event in 2018 and 1st Hematology/Coagulation testing event in 2019.</p>
<p>D2130</p>	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive 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), the laboratory failed to achieve successful performance for Hematology testing for multiple analytes. Findings are as follows: The laboratory failed Hematology testing for the following analytes in two consecutive PT events: - Cell Identification or White Blood Cell Differential - Erythrocyte Count - Hematocrit - Hemoglobin - Leukocyte Count - Platelet Count - Partial Thromboplastin Time - Prothrombin Time Two consecutive PT failures for the same analyte constitutes unsuccessful performance. PT reports from API listed the following unsatisfactory scores for each of the analytes listed above. - 2018 Hematology/Coagulation 3rd event: 0% - 2019 Hematology/Coagulation 1st event: 0%</p>
<p>D2131</p>	<p>HEMATOLOGY CFR(s): 493.851(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on proficiency testing (PT) scores from the American Proficiency Institute (API), the laboratory failed to achieve satisfactory performance for multiple Hematology analytes in two consecutive testing events, constituting unsuccessful performance for each analyte. Review of results from API revealed that the laboratory had unsatisfactory performance for the following Hematology analytes in two</p>

consecutive PT events, leading to unsuccessful performance. - Cell Identification or White Blood Cell Differential - Erythrocyte Count - Hematocrit - Hemoglobin - Leukocyte Count - Platelet Count - Partial Thromboplastin Time - Prothrombin Time Unsatisfactory PT performance for each of the analytes listed above was obtained in the following events. - 2018 Hematology/Coagulation 3rd event: 0% - 2019 Hematology/Coagulation 1st event: 0% .