

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0403629	(X3) Date Survey Completed 07/16/2019
Name of Provider or Supplier Community Memorial Hospital	Street Address, City, State 512 Skyline Blvd, Cloquet, 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, College of American Pathologists (CAP) proficiency testing reports, and email communication with the Technical Consultant, the laboratory failed to successfully participate in proficiency testing (PT) for Prothrombin Time (ProX) testing under the specialty of Hematology. Findings are as follows: D2123 - the laboratory failed to obtain a PT score of at least 80 percent for Prothrombin Time (ProX) testing. D2127 - the laboratory failed to submit PT results for the CAP GCL-A 2019 testing event . D2130 - the laboratory failed to achieve successful PT performance for Prothrombin Time (ProX) testing in two consecutive PT events. .</p>

<p>D2121</p>	<p>HEMATOLOGY CFR(s): 493.851(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 review of proficiency testing (PT) reports from the College of American Pathologists (CAP), the laboratory failed to obtain a PT score for Prothrombin Time (ProX) of at least 80 percent which resulted in unsatisfactory performance for the analyte. Unsatisfactory PT performance of Prothrombin Time (ProX) was obtained in the following CAP events. - GCL-A 2019 0% - GCL-B 2019 0%</p>
<p>D2123</p>	<p>HEMATOLOGY CFR(s): 493.851(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a 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.</p> <p>This STANDARD is not met as evidenced by: . Based on a review of proficiency testing (PT) reports from the College of American Pathologists (CAP) provider, the laboratory failed to participate in one PT event for Prothrombin Time (ProX) testing. Findings are as follows: The laboratory failed to participate in Prothrombin Time (ProX) PT for the GCL-A 2019 event . Failure to participate in the testing event resulted in unsatisfactory performance for the analyte.</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 review of proficiency testing (PT) reports from the College of American Pathologists (CAP), the laboratory failed to achieve successful PT performance for Prothrombin Time (ProX) testing in two consecutive PT events. Findings are as follows: The laboratory received unsatisfactory scores for Prothrombin Time (ProX) testing in two consecutive PT events. Two consecutive PT failures for the same analyte constitutes unsuccessful performance. PT reports from CAP listed the following unsatisfactory Prothrombin Time (ProX) scores. - GCL-A 2019 0% - GCL-B 2019 0% .</p>