

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0410407	(X3) Date Survey Completed 01/27/2026
Name of Provider or Supplier St Peters Health	Street Address, City, State 2475 Broadway, Helena, MT	
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
D0000	A proficiency testing desk review was completed on January 27, 2026. At the time of the desk review, it was determined that the laboratory was not in compliance with all conditions required by the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 Code of Federal Regulations, Part 493 (42 C.F.R. 493). The following condition level deficiencies were cited: 493.803 Condition: Successful participation.
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 the Certification and Survey Provider Enhanced Reporting (CASPER) 0155 report and records from the College of American Pathologists (CAP) and the Wisconsin State Laboratory of Hygiene (WSLH), the laboratory failed to</p>

	<p>successfully participate in a proficiency testing program approved by HHS for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory failed to successfully participate in the specialties of General Immunology for the analyte Rheumatoid Factor (qualitative) and Hematology for the analyte Hemoglobin (Refer to D2084 and D2130).</p>
<p>D2084</p>	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(f)</p> <p>(f) 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 proficiency testing desk review of the CASPER 0155 report and 2025 College of American Pathologists (CAP) proficiency testing records, the laboratory failed to achieve satisfactory performance (80% or greater) for the same analyte for two consecutive proficiency testing events in the specialty of General Immunology for the analyte Rheumatoid Factor (qualitative). Findings: 1. Review of the CASPER 0155 report revealed the following results: General Immunology 2025 - 2nd Event: The laboratory received an unsatisfactory score of 0% for qualitative Rheumatoid Factor. General Immunology 2025 - 3rd Event: The laboratory received an unsatisfactory score of 0% for qualitative Rheumatoid Factor. 2. Review of the CAP proficiency testing records (S-B 2025 and S-C 2025 Diagnostic Immunology) confirmed the laboratory received the above results.</p>
<p>D2130</p>	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>(f) 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 proficiency testing desk review of the CASPER 0155 report and 2025 Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing records, the laboratory failed to achieve satisfactory performance (80% or greater) for the same analyte for two consecutive proficiency testing events in the specialty of Hematology for the analyte Hemoglobin (HGB). Findings: 1. Review of the CASPER 0155 report revealed the following results: Hematology 2025 - 2nd Event: The laboratory received an unsatisfactory score of 60% for Hemoglobin. Hematology 2025 - 3rd Event: The laboratory received an unsatisfactory score of 0% for Hemoglobin. 2. A review of proficiency testing records from WSLH 2025 proficiency testing records (2025 BloodGas2 and BloodGas3) confirmed the above findings.</p>
<p>D5211</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p>

This STANDARD is not met as evidenced by:

Based on 2025 Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing records and an email communication with the laboratory manager, the laboratory failed to review and evaluate two of two Blood Gas proficiency testing events performed on the Abbott i-STAT blood analyzer for year 2025. Findings: 1. The laboratory failed to review the WSLH proficiency testing Performance Summary for 2025 BloodGas2 and BloodGas3 as required by its policy, "Laboratory Proficiency Testing LAB-0020.B." 2. The laboratory failed to perform an investigation and document its corrective actions for unacceptable proficiency testing results for 2025 BloodGas2 and BloodGas3 as required by its policy, "Laboratory Proficiency Testing LAB-0020.B."(Cross-reference D2130). 3. An email communication on January 26, 2026, at 4:44 PM with the laboratory manager stated: "They were unable to locate and had no information from the POC Coordinator."