

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  35D0041814	<b>(X3) Date Survey Completed</b>  04/01/2026
<b>Name of Provider or Supplier</b>  Smp Health St Aloisius	<b>Street Address, City, State</b>  325 Brewster St E, Harvey, ND	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5215</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to verify the accuracy of results for 1 of 3 microbiology events in 2025 (2nd Event) the American Proficiency Institute (API) assigned as not graded. The laboratory performed 327 susceptibility testing patient tests in the past year. Findings include: 1. Reviewed at 9:43 a.m. on 04/01/26, the 2nd Event 2025 Microbiology proficiency testing showed combination antibiotics Ticarcillin/Clavulanate as not graded for Susceptibility Testing sample BL-01, Susceptibility A sample UR-06, and Susceptibility B sample UR-07. The laboratory failed to evaluate the not graded results. 2. During an interview at 12:08 p.m. on 04/01/26, a laboratory manager (#1) confirmed the laboratory failed to evaluate the 2nd Event 2025 Ticarcillin/Clavulanate Susceptibility Testing, Susceptibility A, and Susceptibility B not graded results. 3. The laboratory failed to provide a policy regarding verification of accuracy of results for proficiency testing.</p>
<b>D5221</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on record review and staff interview, the laboratory failed to verify the accuracy of results for 1 of 3 microbiology events in 2025 (2nd Event) the American Proficiency Institute (API) assigned as unacceptable. The laboratory performed 327 susceptibility testing patient tests in the past year. Findings include: 1. Reviewed at 9:43 a.m. on 04/01/26, the 2nd Event 2025 Microbiology proficiency testing Susceptibility Testing records failed to show the laboratory documented verification of accuracy for sample BL-01 antibiotic Imipenem and combination antibiotics Trimethoprim/Sulfamethoxazole. 2. During an interview at 12:08 p.m. on 04/01/26, a laboratory manager (#1) confirmed the laboratory failed to document review of the 2nd Event 2025 Imipenem and Trimethoprim/Sulfamethoxazole Susceptibility Testing unacceptable results. 3. The laboratory failed to provide a policy regarding verification of unacceptable proficiency testing.

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**

CFR(s): 493.1254(a)(1)

(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to perform required quarterly maintenance for 4 of 4 quarters (1st quarter 2025 [January 2025 through March 2025], 2nd quarter 2025 [April 2025 through June 2025], 3rd quarter 2025 [July 2025 through September 2025], and 4th quarter 2025 [October 2025 through December 2025]) reviewed. The laboratory performed 478 PT/INR (Prothrombin Time /International Normalized Ratio) and 145 PTT (Partial Thromboplastin Time) patient tests in the past year. Findings include: 1. Reviewed at 2:52 p.m. on 04/01/26, the Sysmex CA 600 Operator's Maintenance Checklist showed the quarterly maintenance "Clean DI (deionized) Water Rinse Bottle with Alcohol". 2. Reviewed the afternoon of 04/01/26, the January 2025 through December 2025 maintenance checklists for the Sysmex CA 600 series lacked evidence of the quarterly "Clean DI Water Rinse Bottle with Alcohol" maintenance performance. 3. During an interview at 2:57 p.m. on 04/01/26, a laboratory manager (#1) confirmed the laboratory failed to complete quarterly "Clean DI Water Rinse Bottle with Alcohol" maintenance on the Sysmex CA 600 series in January 2025 through December 2025.

**D6120**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(7)(8)

(b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the technical supervisor failed to evaluate the competencies for all non-waived test systems for 1 of 5 testing personnel (#1) in 2025. Failure to evaluate the competency of testing personnel limits the laboratory's ability to ensure testing personnel perform patient tests correctly to produce accurate and reliable results. Findings include: 1. Reviewed at 11:11 a.m. on 04/01/26, the

2025 competency evaluation records for testing personnel (#1) lacked evidence of evaluation of the following elements for the listed non-waived testing systems: \*

Testing Personnel (#1): - Dimension EXL chemistry analyzer: direct observation of test performance, review of maintenance records, direct observation of maintenance, and assessment of problem solving skills - Stratus CS chemistry analyzer: direct observation of test performance, review of maintenance records, direct observation of maintenance, review of quality control, and assessment of problem solving skills - Epoc blood gas analysis system: review of patient test results, direct observation of test performance, review of quality control, and assessment of problem solving skills - Sysmex XS-1000i hematology analyzer: direct observation of test performance, review of maintenance records, direct observation of maintenance, and assessment of problem solving skills - Manual differentials: review of patient test results, direct observation of test performance, and assessment of problem solving skills - Diesse Minicube automated erythrocyte sedimentation rate analyzer: direct observation of test performance and assessment of problem solving skills - Urine microscopic examination: direct observation of test performance and assessment of problem solving skills - Sysmex CA 600 series coagulation analyzer: direct observation of test performance, review of maintenance records, direct observation of maintenance, review of quality control, and assessment of problem solving skills - Microbiology culture/minimum inhibitory concentration (MIC) procedures: review of patient test results, direct observation of test performance, review of maintenance records, direct observation of maintenance, review of quality control, and assessment of problem solving skills - Alere Clostridioides difficile (C. diff): review of patient test results, direct observation of test performance, review of quality control, and assessment of problem solving skills - Gram stain procedures: review of patient test results, direct observation of test performance, review of quality control, and assessment of problem solving skills - Blood culture procedures: review of patient test results, direct observation of test performance, and assessment of problem solving skills - Immunohematology crossmatch and direct antiglobulin test (DAT) procedures: direct observation of test performance, review of quality control, and assessment of problem solving skills

2. During an interview the afternoon of 04/01/26, a laboratory manager (#1) confirmed the 2025 competency evaluation for testing personnel (#1) failed to include all elements. 3. The laboratory failed to provide a policy regarding the six testing personnel competency assessment procedures.

**D6128**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1451(b)(9)

(b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:  
Based on record review and staff interview, the technical supervisor failed to evaluate and document the competency for 5 of 5 testing personnel (Testing Personnel #1, #2, #3, #4, and #5) requiring annual competency evaluations in 2025. Findings include: 1. Reviewed at 11:11 a.m. on 04/01/26, the competency evaluation records lacked evidence of annual competency evaluations in 2025 as follows: - Testing Personnel (#1) - post vasectomy semen analysis, ABO blood group, Rh factor, and antibody screen - Testing Personnel (#2) - post vasectomy semen analysis, ABO blood group, Rh factor, and antibody screen - Testing Personnel (#3) - Sysmex CA 600 series

coagulation analyzer, post vasectomy semen analysis, ABO blood group, Rh factor, and antibody screen - Testing Personnel (#4) - post vasectomy semen analysis, ABO blood group, Rh factor, and antibody screen - Testing Personnel (#5) - post vasectomy semen analysis, ABO blood group, Rh factor, and antibody screen 2. During interview at 12:22 p.m. on 04/01/26, a laboratory manager (#1) confirmed testing personnel (#3) did not have all annual competency evaluations completed in 2025. 3. The laboratory failed to provide a policy regarding annual competency evaluations.