Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	35D0408653	02/04/2026
Name of Provider or Supplier	**Street Address, City, State**	
Smp Health St Andrew's	316 Ohmer St, Bottineau, ND	

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
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, policy review, and staff interview, the laboratory failed to perform required monthly maintenance for 2 of 2 manufacturers (Cardinal Health Premier Plus Blood Bank Refrigerator and Vitros 4600) reviewed. The laboratory performed 220 blood bank patient tests and 94,126 patient tests on the Vitros 4600 analyzer the past year. Findings include: 1. Reviewed at approximately 1:45 p.m. on 02/04/26, the Cardinal Health Premier Plus Blood Bank Refrigerator maintenance log showed the following monthly checks: "High Temp Check Temp High LED Lit Alarm Sounded NS [Nursing] Responded Low Temp Check Temp Low LED Lit Alarm Sounded NS Responded Door Ajar Door Ajar LED Flashes Alarm Sounded NS Responded Battery Check Continuous LED Date Initials" 2. Reviewed at approximately 1:45 p.m. on 02/04/26, the April 2025 and October 2025 maintenance logs for the Cardinal Health Premier Plus Blood Bank Refrigerator lacked evidence of monthly maintenance performance. 3. Reviewed the afternoon of 02/04/26, the "Blood Bank Refrigerator" policy, effective 01/2021, stated, "Record the following on the Cardinal Health Premier Plus Blood Bank Refrigerator Maintenance Log. 1. Simulated Alarm Test. . . . 2. Door ajar alarm check. . . ." 4. During an interview the afternoon on 02/04/26, the Laboratory Manager (#1) confirmed the laboratory had not completed the monthly maintenance for the Cardinal Health Premier Plus Blood Bank Refrigerator in April 2025 and October 2025. 5. Reviewed at approximately 2:30 p.m. on 02/04/26, the Vitros 4600 maintenance log showed the following maintenance procedures: "Clean Versa Tip Supply Inspect/Clean Supply 3 Pack Opener Inspect /Clean Supply 3 Ring Inspect/Clean Supply 3 Housing/Cover Clean Supply 3 Tub including Barcode Reader Window Clean Cuvette Arm Clean Cuvette Incubator

	Clean PM Discard Chute Clean PM Incubator Slot and Insert Blade Channels Clean /Replace PM Evaporation Caps Clean MicroSensor Cover and Ring Area" 6. Reviewed at approximately 2:30 p.m. on 02/04/26, the September 2025 maintenance log for the Vitros 4600 lacked evidence of monthly maintenance procedures. 7. During an interview at 2:52 p.m. on 02/04/26, the Laboratory Manager (#1) confirmed she expected staff to complete monthly maintenance on the Vitros 4600.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) (a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following: This STANDARD is not met as evidenced by: Based on observations, manufacturer instructions review, staff interview, and record review, the laboratory failed to perform required function checks [calibration and quality checks] on 1 of 1 blood bank pipette (ID-TIPMASTER Repetitive Dispense Pipetor) observed. Findings include: 1. Observation at approximately 7:48 a.m. on 02 /04/26 showed a blood bank pipette on a counter at the blood bank bench with no function check date. 2. Reviewed on 02/04/26, the "Instructions for Use ID-TIPMASTER Repetitive Dispense Pipetor", stated, "Before using the ID-TIPMASTER Pipetor in a laboratory environment, perform a calibration check in accordance with the QUALITY CHECK section . . . Service and Maintenance . . . It is recommended that the following maintenance procedure be performed at regular intervals. . . . After the above maintenance procedure, perform a QUALITY CHECK . . ." 3. During an interview at 4:28 p.m. on 02/04/26, the Laboratory Manager (#1) failed to identify the date of the ID-TIPMASTER Repetitive Dispense Pipetor's last calibration and quality checks. 4. Reviewed at 5:17 p.m. on 02/04/26, preventative maintenance records lacked evidence of ID-TIPMASTER Repetitive Dispense Pipetor calibration and quality checks. 5. Upon request, the laboratory failed to provide procedures for frequency of calibration and quality checks on the ID-TIPMASTER Repetitive Dispense Pipetor.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by:

	Based on record review, quality control plan review, and staff interview, the laboratory failed to follow their Individualized Quality Control Plan (IQCP) for quality control (QC) performance for 2 of 6 QC periods reviewed (04/29/25 through 06/19/25 and 08/14/25 through 09/25/25) for D-Dimer testing on the Triage Meter Pro. The laboratory performed 157 patient D-Dimers the past year. Findings include: 1. Reviewed at 3:26 p.m. on 02/04/26, the QC records for D-Dimer performed on the Triage Meter Pro indicated the laboratory failed to perform two levels of QC on 05/29 /25 and 09/14/25 as stated in the laboratory's IQCP. 2. Reviewed at 3:26 p.m. on 02/04 /26, the laboratory's D-Dimer IQCP, last reviewed 01/2026, stated "QC will be performed every 30 days and with each new lot/shipment." 3. During interview at 3: 45 p.m. on 02/04/26, the Laboratory Manager (#1) confirmed the laboratory's IQCP for D-Dimers on the Triage Meter Pro required performance of two levels of QC every 30 days and the laboratory failed to perform two levels of QC every 30 days.
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 observations, record review, staff interview, and policy review, the Technical Supervisor failed to evaluate and document the competency for 1 of 4 testing personnel (Laboratory Manager #1) requiring annual competency evaluations in 2024 and 2025. Findings include: 1. Observations made the morning of 02/04/26 showed the Laboratory Manager (#1) performing patient testing. 2. Reviewed at 9:45 a.m. on 02/04/26, the competency evaluation records lacked evidence of annual competency evaluations in 2024 and 2025 for the Laboratory Manager (#1). 3. During an interview at 1:10 p.m. on 02/04/26, the Laboratory Manager (#1) confirmed she did not have annual competency evaluations completed in 2024 and 2025. 4. Reviewed the afternoon of 02/04/26, the "Lab Policy Manual" revised 02/01/21, stated, "The technical supervisor is responsible for the technical and scientific oversight of the laboratory. . . . Evaluating and documenting the performance of individuals responsible for high complexity testing . . . at least annually . . ."