Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	35D0408653	04/11/2018
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review, staff interview, and policy review, the laboratory failed to ensure the laboratory director signed the attestation statements for 11 of 15 (1-2017 immunohematology; 2-2017 core chemistry, hematology, immunohematology; 3-2017 core chemistry, hematology, microbiology, immunohematology; 1-2018 core chemistry, hematology, and microbiology) proficiency testing events reviewed from January 2017 through March 2018. Findings include: 1. Reviewed at 1:40 p.m. on 04/10/18, the January 2017 through March 2018 proficiency testing records lacked evidence the laboratory director or qualified designee signed the proficiency testing attestation statements for the following eleven events: 1-2017 immunohematology; 2-2017 core chemistry, hematology, immunohematology; 3-2017 core chemistry, hematology, microbiology, immunohematology; 1-2018 core chemistry, hematology, and microbiology. 2. During an interview at 4:10 p.m. on 04/10/18, the laboratory supervisor (#1) confirmed the laboratory director or qualified designee had not signed the eleven proficiency testing attestation statements listed above. 3. Reviewed at 11:15 a.m. on 04/11/18, the undated policy "General Quality Control (Includes Proficiency Testing Policy)," failed to include a requirement for the laboratory director or qualified designee to sign the proficiency testing attestation statements.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system

	must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review, staff interview, and policy review, the laboratory failed to verify the reportable range for 2 of 4 urine chemistry analytes (creatinine and sodium) on the new Ortho Vitros 4600 chemistry analyzer in 2016. The laboratory performed approximately 245 urine creatinine patient tests since implementation on 10/01/16 and 4 urine sodium patient tests since implementation on 02/02/17. Findings include: 1. Reviewed at 7:05 a.m. on 04/11/18, the laboratory's 2016 performance specification verification records for the new Ortho Vitros 4600 chemistry analyzer lacked evidence the laboratory verified the reportable range for urine creatinine and urine sodium. 2. During interview at approximately 9:45 a.m. on 04/11/18, the laboratory supervisor (#1) confirmed the laboratory performed patient testing for urine creatinine and urine sodium on the Ortho Vitros 4600 chemistry analyzer and had not verified the reportable range. 3. Reviewed at approximately 12:15 p.m. on 04/11/18, the undated policy "Method Verification," stated, ". . . Reprotable [sic] Range (Linearity) The laboratory is responsible for verifying the reportable range of patient test results of each test system. . . ."
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to verify calibration for 1 of 1 Ortho Vitros 4600 analytes (chloride) calibrated with less than three calibrators at least once every six months in 2017. Findings include: 1. Reviewed at

	approximately 7:30 a.m. on 04/11/18, the Ortho Vitros 4600 calibration records indicated the laboratory used two standards to calibrate chloride. 2. Reviewed the morning of 04/11/18, the 2017 calibration verification records lacked evidence the laboratory verified calibration for chloride in 2017. 3. Upon request on 04/11/18, the laboratory failed to provide evidence of calibration verification for chloride in 2017. 4. During interview at approximately 8:30 a.m. on 04/11/18, the laboratory supervisor (#1) stated the laboratory used two standards for calibration of chloride and confirmed the laboratory had not verified calibration of chloride in 2017. 5. Upon request on 04 /11/18, the laboratory did not provide a policy regarding calibration verification requirements.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (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, staff interview, and policy review, the technical consultant failed to include the Biosite Triage Meter analyzer in the annual competency evaluation for 1 of 2 sampled testing personnel (#1) in 2017. Findings include: 1. Reviewed at 4:30 p.m. on 04/10/18, the 2017 competency evaluation records for Testing Personnel #1 lacked evidence of a completed competency evaluation for the BiositeTriage Meter analyzer. 2. During an interview at 9:45 a.m. on 04/11/18, the laboratory supervisor (#1) confirmed the competency evaluation for Testing Personnel #1 in 2017 did not include the Biosite Triage Meter analyzer. 3. Reviewed at 11:15 a. m. on 04/11/18, the policy "Laboratory Job Descriptions," revised 8/06/08, stated, ". . . Job Title: Technical Supervisor . . . Responsibilities . . . 9. Evaluating and documenting the performance of individuals responsible for high complexity testing . . . evaluations must be performed at least annually . . ."