Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	35D0408653	06/04/2024
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
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 observation, staff interview, and policy review, the laboratory failed to verify the manufacturer's performance characteristics for 1 of 1 new endocrinology test method (serum pregnancy) in 2023 before reporting patient results. The laboratory performed 47 patient tests with the new test kit since implementation on 05/13/23. Findings include: 1. Observation of the laboratory at 09:15 a.m. on 06/04/24 showed a Cardinal Health hCG (human chorionic gonadotropin) Combo Rapid Test available for patient pregnancy testing. 2. Upon request on 06/04/24, the laboratory failed to provide evidence of verification of performance characteristics for the new serum pregnancy testing method (Cardinal Health hCG Combo Rapid Test). 3. During interview at 3:55 p.m. on 06/04/24, a general supervisor (#1) confirmed the laboratory began patient testing using a new serum pregnancy test kit (Cardinal Health hCG Combo Rapid Test) on 05/13/23, and the laboratory did not verify the manufacturer's performance characteristics before patient testing began. 4. Reviewed on 06/04/24, the undated policy "Method Verification," stated, "Purpose: The laboratory must have written protocol and documentation for the validation of each method, which verifies patient correlation, accuracy, precision, reportable range, and reference range for each

	new unmodified, moderate complexity test that the laboratory performs. The verification process helps to assure that the test . . . is performing as the manufacturer intended. . . ."
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) 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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review, staff interview, and policy review, the laboratory failed to perform a positive and negative control each day of patient testing for serum pregnancy tests for 4 of 5 patient testing days (04/03, 04/09, 04/30, and 05/23) in April-May 2024. The laboratory performed five serum pregnancy tests on days with no quality control (QC) performance in April-May 2024. Findings include: 1. Reviewed on 06/04/24, the patient testing records for serum pregnancy indicated performance of patient testing using the Cardinal Health hCG (human chorionic gonadotropin) Combo Rapid Test on the following days in April-May 2024: - 04/03 one patient test, - 04/09 one patient test, - 04/29 one patient test, - 04/30 two patient tests, and - 05/23 one patient test. 2. Reviewed on 06/04/24, the April-May 2024 QC records for serum pregnancy failed to include evidence of the performance of positive and negative controls on the following patient testing days: 04/03, 04/09, 04/30, and 05/23. 3. During interview at 3:55 p.m. on 06/04/24, a general supervisor (#1) confirmed the laboratory failed to perform QC each day of patient testing for serum pregnancy using the Cardinal Health hCG Combo Rapid Test. 4. Reviewed on 06/04 /24, the policy "General Quality Control (Includes Proficiency Test Policy)," revised 01/20/24, stated, "Characteristics of a good control Quality control is designed to detect, reduce, and correct deficiencies in a laboratory's internal analytical process prior to the release of patient results. . . . Quality control material is usually run at the beginning of each shift . . . Quantitative/Qualitative QC Qualitative testing, [sic] is usually performed to determine the presence of a specific substance . . . Examples are pregnancy and Strep tests. The results are reported out as positive or negative. . . ."
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review, staff interview, and policy/procedure review, the laboratory

	failed to include the units of measure for 2 of 2 random urine microscopic and prostate specific antigen (PSA) patient reports reviewed (Patients #15139 and #32243). The laboratory reported approximately 250 urine microscopic and 100 PSA patient test results since the start of a new electronic record system March 4, 2024. Findings include: 1. Reviewed on 06/04/24, the following random patient reports failed to include the units of measure: - Patient #15139 on 05/31/24 for PSA and - Patient #32243 on 06/06/24 for white blood cell and red blood cell quantified results. 2. During interview at 4:55 p.m. on 06/04/24, a general supervisor (#1) stated the laboratory began using a new electronic record system March 4, 2024 and confirmed the patient reports for PSA and urine microscopic results failed to include the units of measure. 3. Review of the following undated policies/procedures occurred on 06/04/24: - "Microscopic Results Reporting," stated, ". . . Casts: Enumerate on low power. . . . RBC and WBC: Enumerate the average number/HPF [high power field] . . ." - "Prostate Specific Antigen ST AIA-PACK PA," stated, ". . . Calculation of Results . . . All the AIA Systems read the rate of fluorescence produced by the reaction and automatically convert the rate to Prostate Specific Antigen concentration in ng/mL [nanograms per milliliter]." 4. Reviewed on 06/04/24, the laboratory's general policy manual failed to include a policy defining the elements required for patient test reports.