

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D1038677	(X3) Date Survey Completed 03/04/2021
Name of Provider or Supplier Stevens Community Medical Center-Starbuck Clinic	Street Address, City, State 501 Poler Street, Starbuck, MN	
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
D5211	<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> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to investigate an unacceptable Chemistry proficiency testing (PT) result for 1 analyte in 2020. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 10:05 a.m. on 03/04/21. 2. The laboratory performed PT using the American Proficiency Institute (API) program. 3. The laboratory received an unacceptable Low-Density Lipoprotein (LDL) PT result for 1 of 15 LDL PT challenges completed in 2020. See below. API 2020 Chemistry 3rd event Sample Test Lab result API range CH-13 LDL 63 32-62 4. Investigation of unacceptable PT results was required as established in the Proficiency Testing Procedure located in the 2021 API 3-ring binder. 5. An investigation of the unacceptable PT result was not found during review of laboratory records. The laboratory was unable to provide investigation documentation upon request. 6. In an interview at 12:18 p.m. on 03/04/21, the LD confirmed the above finding.</p>
D5215	<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>

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the laboratory failed to verify the accuracy of one 2020 proficiency testing (PT) result when the PT program did not obtain the agreement required for scoring. Findings are as follows: 1. The laboratory performed manual microscopic analysis of urine sediment testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 10:05 a. m. on 03/04/21. 2. The laboratory performed PT using the American Proficiency Institute (API) provider. 3. One urine sediment result from the third 2020 Hematology PT event was not graded by API due to lack of consensus. See below. Sample ID Analyte US-06 Urine Sediment 4. The API report referred the laboratory to the expected result data summary for evaluation of the non-graded test result. The data summary for the above analyte was not present in laboratory records. Evaluation of the non-graded result was not found in laboratory records. 5. Investigation of non-graded PT results was required as established in the Proficiency Testing Procedure located in the 2021 API 3-ring binder. The laboratory was unable to provide an evaluation of the non-graded result upon request. 6. In an interview at 12:18 p.m. on 03/04/21, the LD confirmed the above finding. .