

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0405733	(X3) Date Survey Completed 01/26/2021
Name of Provider or Supplier Centracare Laboratory Services-Urology	Street Address, City, State 2351 Connecticut Ave S Suite 200, Sartell, 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
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> <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 two 2019 and one 2020 proficiency testing (PT) scores when the PT program did not obtain the agreement required for scoring. Findings are as follows: 1. The laboratory performed Urinalysis testing as indicated on the Clinical Laboratory Improvements (CLIA) Application for Certification Form CMS-116, and as confirmed by the Technical Consultant 2 (TC2) during a tour of the laboratory on 1/26/21, at 9:05 a.m. 2. The laboratory performed proficiency testing (PT) using the American Proficiency Institute (API) as PT provider. 3. The following PT events / samples / test results were not graded by API due to lack of consensus. See below. Event Sample ID Analyte Heme / Coag US-02 Urine Sediment 2019 / 1st UA-02 Urobilinogen Heme / Coag US-06 Urine Sediment 2020 / 3rd 4. The API report referred the laboratory to the expected result data summary for evaluation of the non-graded test results. The data summary for the above analytes were not present in laboratory records. Evaluation of the non-graded results were not found in laboratory records. The laboratory was unable to provide an evaluation of the non-graded results upon request. 5. In an interview on 1/26/21, at 9:35 a.m., TC2 confirmed the above finding .</p>