

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D2047970	(X3) Date Survey Completed 12/29/2020
Name of Provider or Supplier Sartell Pediatrics	Street Address, City, State 111 2nd Street South, 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 three 2019 proficiency testing (PT) scores when the PT program did not obtain the agreement required for scoring. Findings are as follows: 1. The laboratory performed Hematology and Urinalysis testing as confirmed by the Testing Personnel 1 (TP1) during a tour of the laboratory on 12/29/20, at 10:05 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 Heme / Coag QBC-06 WBC Count 2019 / 2nd Heme / Coag QBC-15 WBC Count 2019 / 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 12/29/20, at 10:45 p.m., TP1 confirmed the above finding .</p>