

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D2047970	(X3) Date Survey Completed 09/11/2018
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
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 evaluate an unacceptable proficiency testing (PT) result. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 09/11/18 at 10:05 a.m. 2. The laboratory performed PT using the American Proficiency Institute (API) PT provider. 3. The laboratory received an unacceptable PT result from API in the third Hematology event of 2018 for White Blood Cell count. See below Event Sample ID Lab result API range 2017-3 QBC-12 25.8 27.2-37.0 4. An evaluation of the unacceptable PT result was not found during review of laboratory records. The laboratory was unable to provide an evaluation upon request. 5. In an interview on 09/11/18 at 11:25 a.m., TP1 confirmed an evaluation of the unacceptable result was not performed.</p>
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory</p>

failed to verify the accuracy of a non-graded proficiency testing (PT) result. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Testing Personnel 1 (TP1) during a tour of the laboratory on 09/11/18 at 10:05 a.m. 2. The laboratory performed PT using the American Proficiency Institute (API) PT provider. 3. The laboratory received non-graded results from API due to no consensus in the first Hematology event of 2018 for White Blood Cell count. The laboratory's result was not within the API expected range. See below Event Sample ID Lab result API range 2018-1 QBC-04 19.3 20.5-27.9 4. An evaluation of the non-graded PT result was not found during review of laboratory records. The laboratory was unable to provide an evaluation upon request. 5. In an interview on 09/11/18 at 11:25 a.m., TP1 confirmed an evaluation of the non-graded PT result was not performed.