

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0404587	(X3) Date Survey Completed 01/25/2018
Name of Provider or Supplier Gundersen Spring Grove Clinic	Street Address, City, State 123 5th Avenue Southeast, Spring Grove, 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
D5807	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.</p> <p>This STANDARD is not met as evidenced by: .. Based on observation, document review and interview with laboratory personnel, the laboratory failed to ensure reference intervals were consistent between procedure and patient test report. Findings are as follows: 1. The laboratory performed Coagulation testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory on 1/25/18 at 10:05 a.m. 2. A Roche CoaguChek XS Pro coagulation analyzer was observed as present and available for use during the tour. 3. The reference interval listed in the PT-INR* Whole Blood Using CoaguChek XS Plus or Pro Test System Procedure, located in the on-line Procedure Manual, was not consistent with that included on the patient test report (MRN = 1843804) reviewed on date of survey, 1/25/18. Analyte Procedure Report INR 0.9 - 1.0 0.8 - 1.1 4. In an interview at 12:15 p.m. on 1/25/18, the LD confirmed the above findings. * PT-INR = Prothrombin Time - International Normalized Ratio .</p>