

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D1018843	(X3) Date Survey Completed 08/27/2025
Name of Provider or Supplier Sanford Luverne Medical Center	Street Address, City, State 1600 N Kniss Ave, Luverne, 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
D0000	<p>. The Sanford Luverne Medical Center laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the recertification survey completed on August 27, 2025. The following standard-level deficiencies were cited: 493.1291 Test report .</p>
D5807	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>(d) 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 one of one qualitative serum hCG (human chorionic gonadotropin) reference intervals were included on a patient test report in 2024 and 2025. Findings are as follows: 1. The laboratory performed qualitative serum hCG testing as indicated on the form CMS-116 provided by the laboratory on the date of survey. 2. Quidel QuickVue hCG combo test kits were observed as present and available for use on patient serum specimens during a tour of the laboratory at 1:05 p. m. on 8/26/25. 3. The qualitative serum hCG reference interval was not listed on a patient test report from 7/2/24 reviewed on the date of survey. 4. The laboratory performed 737 qualitative serum hCG tests in 2024 and 75 qualitative serum hCG tests in 2025. 5. In an interview at 12:41 p.m. on 8/27/25, the Technical Supervisor confirmed the above findings. .</p>