Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2298559	08/14/2024
Name of Provider or Supplier	**Street Address, City, State**	
Bellin Health Surgery & Specialty Center	933 Waube Lane, Green Bay, WI	

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**
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and interview with the technical consultant, the chemistry procedures did not include specific quality control (QC) information and calibration verification procedures for one of one new analyzer reviewed. Findings include: 1. Review of the "Atellica CI 1900 Chemistry Analyzer" chemistry procedure showed no evidence the laboratory included the type, identity, number and frequency of QC material and calibration verification on the Siemens Atellica CI 1900 chemistry analyzer in the procedure. 2. Interview with the technical consultant on August 14, 2024, at 1:30 PM confirmed the chemistry procedures did

	not include specific quality control (QC) information and calibration verification procedures for one of one new analyzer reviewed.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory quality control (QC), patient records and Individualized Quality Control Plan (IQCP) records and interview with the technical consultant, the laboratory did not perform two levels of quality control on each day of patient testing for the OSOM hCG Combo serum pregnancy testing on three of five patient testing days and had not developed an IQCP. Findings include: 1. Review of QC records for the serum pregnancy test showed QC was on March 20, May 14, and July 24, 2024. 2. Review of patient records showed serum pregnancy tests performed on patient on April 16, May 14, June 6, July 24, and July 30, 2024. 3. Review of IQCP records showed no evidence of an IQCP specific for the OSOM hCG Combo serum pregnancy. 4. Interview with the technical consultant on August 14, 2024, at 2: 40 PM confirmed the laboratory did not perform two levels of quality control on each day of patient testing and had not developed an IQCP for the OSOM hCG serum pregnancy test.