Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0921590	10/07/2021
Name of Provider or Supplier	**Street Address, City, State**	
Women's Care Of Wisconsin	5485 Grande Market Dr, Appleton, 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 test procedures and interview with testing personnel, review of three procedures revealed one procedure did not specify which controls were required and a second procedure did not include reference intervals (normal values) or reportable ranges. Findings include: 1. Review of three laboratory procedures including the procedures for Beta Human Chorionic Gonadotropin (B-hCG) and the Chemistry analyzer (ACE Axcel) revealed the following: The "Vitros Immunodiagnostic Products Total B-hCG II Reagent Pack" procedure did not specify which two levels of the three available control materials were required. The "ACE

	Axcel Operation Policy and Procedure" did not include reference intervals or reportable ranges for the tests performed on this platform. 2. Interview with testing personnel (staff A) on October 7, 2021 at 10:00 AM confirmed the B-hCG procedure did not specify which controls were required and interview at 11:00 AM confirmed reference intervals and reportable ranges were not included in the procedure for the chemistry analyzer. This is a repeat deficiency previously cited on September 23, 2019.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) program reports and laboratory PT records from 2020 and 2021, and interview with testing personnel, the laboratory director did not ensure an approved corrective action plan was followed for two of three analytes the PT program identified as having unacceptable results. Findings include: 1. Review of PT program reports from 2020 and 2021 showed three analytes with unacceptable results including: 2020 Event one: Albumin: Sample CH-01, laboratory reported 7.0 g/dL (grams per deciliter) acceptable result range 7.1 - 8.7 25OH- Vitamin D, Sample IAS-04 laboratory reported 84 ng/mL (nanograms per milliliter) acceptable result range 85 - 105 2021 Event one: DHEA-S (dihydroepiandosterone-sulfate) Sample IA-02 laboratory reported 61.7 ug/dL (micrograms per deciliter) expected 61.8 - 75.8 2. Review of the laboratory's PT records showed no evidence of evaluation of the two unacceptable results from the first chemistry event in 2020. 3. Interview with testing personnel (staff A) at 11:15 AM on October 7, 2021 confirmed the two unacceptable results from the first chemistry event in 2020 were not evaluated and the laboratory director did not ensure an approved corrective action plan was followed for these two results.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on surveyor review of quality assurance procedures and records and interview with testing personnel, the laboratory director did not ensure two of two Individualized Quality Control Plans (IQCP) were reviewed yearly in 2020. Findings include: 1. The laboratory's quality assurance procedure states, "IQCP plans will be

	reviewed on a yearly basis to monitor the effectiveness of the IQCP". 2. Review of IQCP records for the BD Affirm showed quality assurance reviews were completed in December 2019 and September 2021. No evidence of review in 2020 is available. Review of IQCP records for the Cepheid Group B Strep and Chlamydia and GC multiplex tests showed quality assurance reviews were completed in September 2021. No records of review in 2020 were available. 3. Interview with testing personnel (staff A) on October 7, 2021 at 11:00 AM confirmed the IQCP plans were not reviewed yearly in 2020. This is a repeat deficiency previously cited on September 23, 2019.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on surveyor review of competence evaluations and interview with testing personnel, the performance of one of two testing personnel was not documented one of the last two years. Findings include: 1. Review of competence evaluation records showed no documented evidence of evaluation of staff A in 2020. 2. Interview with testing personnel (staff A) on October 7, 2021 at 10:00 AM confirmed evaluation of their competence was not documented in 2020.