Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0921590	09/23/2019
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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on surveyor review of proficiency testing records, Laboratory Personnel Report (CLIA) Form CMS-209 (Centers for Medicare and Medicaid Services), and procedures, and interview with the technical consultant, the laboratory referred provider performed microscopy proficiency testing images to another laboratory. Findings include: 1. The laboratory referred proficiency testing images for provider performed microscopy to another laboratory. See D 2013.
D2013	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(4) The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample

	were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason. This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing records, Laboratory Personnel Report (CLIA) Form CMS-209 (Centers for Medicare and Medicaid Services), and procedures, and interview with the technical consultant, the laboratory referred proficiency testing images for provider performed microscopy to another laboratory for analysis for one event in 2018 and two events in 2019. Findings include: 1. Review of proficiency testing records showed the laboratory reported results for fern testing, vaginal wet prep and vaginal KOH (potassium hydroxide) provider performed microscopy tests. Review of the attestation statement for event two in 2018 showed staff A performed these tests on July 17, 2018. The attestation statements for events one and two in 2019 showed staff A performed the testing for event one on March 27, 2019 and event two on July 18, 2019. 2. Review of the Laboratory Personnel Report (CLIA) Form CMS-209 provided during survey and signed by the laboratory director on September 23, 2019, showed the report did not include staff A as testing personnel in this laboratory. 3. The laboratory's "Proficiency Testing" procedure (approved December 23, 2015) states, "The Lab cannot send PT samples to another lab for testing." 4. Staff A from Women's Care of Wisconsin-CLIA #52D2149063 performed proficiency testing for fern, vaginal wet prep and vaginal KOH provider performed microscopy testing for event 2 in 2018 and event 1 and 2 in 2019 on proficiency test kits that were issued to Women's Care of Wisconsin-CLIA ID# 52D0921590 and signed the proficiency testing attestation statement for Women's Care of Wisconsin-CLIA #52D0921590. The proficiency testing results performed by Staff A at Women's Care of Wisconsin-CLIA ID #52D2149063 were then submitted to the proficiency testing provider as samples from Women's Care of Wisconsin-CLIA #520921590 prior to the proficiency testing due date. In an interview with the Technical Consultant, it was confirmed that the proficiency testing samples issued to CLIA ID #52D0921590 for fern, vaginal wet prep and vaginal KOH provider performed microscopy testing for proficiency testing event 1 in 2018 and events 1 and 2 in 2019 were physically taken by the Technical Consultant to Women's Care of Wisconsin-CLIA ID#52D2149063, another CLIA certified laboratory, for analysis and reported the proficiency testing results to the proficiency testing provider prior to the due date for submission. The interview occurred on September 23, 2019 at 10:30 AM and 11:35 AM.
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 "Serum Pregnancy Test Policy" does not identify the frequency for testing external quality controls. Findings include: 1. Review of the "Serum Pregnancy Test Policy" (approved December 18, 2018) revealed the procedure did not identify the testing frequency for external controls. 2. Interview with the technical consultant on September 23, 2019 at 3:00 PM confirmed the procedure for serum pregnancy testing did not include the frequency for testing external quality controls.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of the Individualized Quality Control Plans (IQCP) for the Cepheid GeneXpert and BD Affirm test systems, the laboratory's IQCPs did not specify the required testing frequency of external quality controls. Findings include: 1. Review of the IQCPs for the Cepheid GeneXpert and BD Affirm test systems showed the IQCPs did not identify the required testing frequency of external quality controls. 2. Interview with the technical consultant on September 23, 2019 at 3:15 PM confirmed the laboratory's IQCPs did not identify the required testing frequency of external quality controls.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following

	for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of serum pregnancy testing and quality control records and interview with the technical consultant, the laboratory did not test a negative and positive control each day patient samples were tested, and did not develop an Individualized Quality Control Procedure (IQCP). Findings include: 1. Review of serum pregnancy testing records from July through September 2019 showed the laboratory tested fourteen patient samples on eleven separate days. 2. Review of external quality control records from July through September 2019 showed the laboratory only tested external controls on one of the eleven days when the laboratory tested patient samples. 3. Interview with the technical consultant on September 23, 2019 at 1:30 PM revealed the laboratory did not test positive and negative external serum pregnancy controls each day of patient testing. Further interview confirmed the laboratory had not developed an IQCP for serum pregnancy testing.
D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of control records for the RPR (Rapid Plasma Reagin) test and interview with the technical consultant, the laboratory had not tested a control with a known titer when performing RPR titers on patient samples. Findings include: 1. Review of control records for the RPR test showed no evidence the laboratory tested a control with a known titer when titering positive patient samples. 2. Interview with the technical consultant on September 23, 2019 at 3:40 PM confirmed the laboratory did not test a control with a known titer when determining the titer of positive patient samples.
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 laboratory Individualized Quality Control Plans (IQCP) and procedures and interview with the technical consultant, the laboratory had not

	developed quality assessment policies for the evaluation of their IQCPs and had not developed written quality assessment policies and procedures for the laboratory. Findings include: 1. Review of the IQCP documents for the Cepheid GeneXpert and BD Affirm test systems showed no evidence the laboratory had developed written policies for ongoing monitoring of the effectiveness of their IQCPs. 2. Review of laboratory policies and procedures showed no evidence of a written quality assessment plan for the pre-analytic, analytic, or post-analytic processes. 3. Interview with the technical consultant on September 23, 2019 at 4:00 PM confirmed the laboratory had not developed a quality assessment plan for the IQCPs or a general quality assessment plan for the laboratory.