Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0921590	08/14/2025
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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and interview with technical consultant (Staff B), the laboratory director did not approve, sign, and date the individualized quality control plan (IQCP) for one of two IQCPs in use at the time of the survey. Findings include: 1. Review of the laboratory procedure manual revealed an unsigned copy of the "BD Affirm VPIII IQCP" currently in use. 2. Interview with Staff B on August 14, 2025, at 11:40 AM, confirmed that the copy of the "BD Affirm VPIII IQCP" found in the procedure manual was the version currently in use, and that the approved and signed copy of the "BD Affirm VPIII IQCP" was not available.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of the procedure manual, record review, and interview with testing personnel (Staff A), the laboratory did not define the frequency of function checks in

	writing for four of four types of equipment used with the ID-MTS system for blood typing and antibody screen testing to ensure equipment performance for accurate and reliable test results. Findings include: 1. Review of procedure manual for blood typing and antibody screen with the ID-MTS system showed the procedure did not define the frequency of function checks for the equipment. 2. Interview with Staff A on August 14, 2025, at 2:00 PM, revealed that function checks for equipment used to perform blood typing and antibody screen testing are performed every six months. 3. Review of forms titled "ID-MTS Quality Control Records" revealed function checks performed more than six months apart for the most recent two years of records, as follows: 3a. The "MTS Dispenser Periodic Volume Verification Checks" form included documentation of MTS Dispenser volume verification checks performed more than six months apart with dates documented as: 8/15/2023, 4/1/2024, 11/26 /2024, 7/31/2025. 3b. The "MTS Pipettor: Periodic Accuracy and Precision Checks" form included documentation of MTS Pipettor accuracy and precision checks performed more than six months apart with the three pipettor settings (10 microliters (uL), 25 uL, 50 uL) performed as follows: -10 uL: 1/25/2024, 9/23/2024, 6/12/2025 -25 uL: 1/23/2024, 9/20/2024, 6/12/2025 -50 uL: 1/23/2024, 9/23/2024, 6/12/2025 3c. "Ortho Workstation: Periodic (As Needed) Checks" form revealed frequency of testing recorded as "every 6 months" and included documentation of centrifuge speed and timing, and incubator temp and timing performed more than six months apart with dates documented as: 8/25/2023, 4/1/2024, 11/26/2024, 7/31/2024. 4. Interview with Staff A on August 14, 2025, at 2:10 PM, confirmed that the procedure did not define frequency of function checks, and that the laboratory had not performed function checks at the frequency stated by Staff A.
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. This STANDARD is not met as evidenced by: Item 1: Based on review of the procedure manual, observation in the laboratory, and interview with testing personnel (Staff A), the laboratory did not specify the number, type, and frequency of testing control materials in use for one of one rapid plasma reagin (RPR) procedure. Findings include: 1. Review of RPR Testing Procedure, "ASI RPR Card for Syphilis Procedure (September 20, 2021)", revealed that the procedure did not include number, type, and frequency of testing control materials, and steps for conducting quality control on the RPR test system. 2. Observation of the RPR Test Kit in the laboratory on August 14, 2025, at 11:45 AM, revealed kit contents including three vials of controls. 3. Interview with Staff A on August 14, 2025, at 11:50 AM, confirmed that the RPR procedure did not specify the number, type, and frequency of testing control materials in use. Item 2: Based on review of individualized quality control plans (IQCPs), and interview with testing personnel (Staff A), the laboratory did not specify the type of quality control material used for two of two IQCPs.

	Findings include: 1. Review of the "BD Affirm VPIII IQCP" and "X-Pert Risk Assessment Policy IQCP" revealed that the IQCPs did not specify the type of testing control materials used. 2. Interview with Staff A on August 14, 2025, at 11:00 AM, confirmed that the laboratory did not specify the type of external controls required in the two IQCPs.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. This STANDARD is not met as evidenced by: Based on observation in the laboratory, review of the procedure manual, and interview with the testing personnel (Staff A), for one of one type of growth media used in the laboratory, the laboratory did not perform quality control and did not establish a control procedure that includes checking each batch of media for sterility, checking for its ability to support or inhibit growth, and documenting and reporting to manufacturer if batch of media appears compromised or deteriorated prior to use. Findings include: 1. The surveyor observed vials of Lim broth in the laboratory on August 14, 2025, at 11:00 AM. 2. Review of the procedure manual revealed no evidence of a quality control procedure or individualized quality control plan (IQCP) for the Lim broth media used in the procedure for testing Group B Streptococcus (GBS) on the GeneXpert. 3. Interview with Staff A on August 14, 2025, at 1:00 PM, confirmed that the laboratory did not establish a quality control procedure or IQCP, and did not perform quality control testing of the Lim broth media.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the technical consultant (Staff B), the laboratory director did not document competency for technical consultant responsibilities and delegated responsibilities for performing competency assessments for the last two years for three of three staff. Findings include: 1. Review of the competency assessment records revealed that testing personnel (Staff A) had assessed competency for testing personnel (Staff C), and Staff C had conducted the

	observational components of the competency assessment procedures for Staff A in the last two of two years. 2. Review of the laboratory records revealed no evidence that the laboratory director had documented competency for testing personnel (Staff A and Staff C) who had performed competency assessments for other testing personnel. 3. Review of the laboratory records revealed no evidence that the laboratory director had documented competency for technical consultant responsibilities for Staff B. 4. Interview with Staff B on August 14, 2025, at 4:10 PM, confirmed that the laboratory director did not document competency for technical consultant and for testing personnel who conducted competency assessments of other testing personnel for the last two of two years.
D6005	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c) (c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with testing personnel (Staff A), for the year 2025, the laboratory director did not meet the requirement for conducting and documenting an onsite visit for one of one visit required in the first six months of 2025. Findings include: 1. Review of laboratory records revealed that as of August 14, 2025, there was no evidence the laboratory director conducted an onsite visit in the first six months of the year 2025. 2. Interview with Staff A on August 14, 2025, at 4: 05 PM, confirmed that the laboratory director had not yet conducted an onsite visit in 2025.