STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	52D0888142	A. BUILDING _____ B. WING _____	R 11/27/2020

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
MILWAUKEE WOMENS MEDICAL SERVICES	1428 N FARWELL AVE MILWAUKEE, WI 53202

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
{D5217} 130M	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on surveyor review of procedures and laboratory records, and interview with the clinic director, the laboratory has not verified the accuracy of the provider performed microscopy testing performed by the laboratory director. Findings include: 1. Review of laboratory procedures revealed a current procedure for the microscopic evaluation of vaginal wet preparations. 2. Review of laboratory records showed no evidence of proficiency testing or other verification of accuracy for the wet preparation procedure. 3. Interview with the clinic director, staff A, on October 5, 2020 at 11:50 AM confirmed the laboratory director occasionally performs vaginal wet preparation exams. Further interview confirmed the laboratory had no process in place to verify the accuracy of the procedure twice annually.	{D5217}		12/7/20
{D5401} 510M	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.	{D5401}		12/7/20

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE 12/07/2020

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{D5401}	Continued From page 1 This STANDARD is not met as evidenced by: Based on surveyor observation of laboratory test supplies, review of laboratory procedures and interview with the clinic director, the laboratory did not have a written procedure for Rh testing performed with Quotient Anti-D blend reagent since testing started on July 11, 2019. Findings include: 1. Observation of test supplies in the laboratory refrigerator on October 5, 2020 at 11:00 AM revealed Quotient Anti-D blend reagent available for testing. 2. Review of laboratory procedures showed no evidence of a procedure for testing using Quotient Anti-D blend reagent. Further review showed no evidence of the manufacturer's instructions for the Quotient Anti-D blend reagent. 3. Interview with the clinic director, staff A, on October 5, 2020 at 11:30 AM confirmed the laboratory started using Quotient Anti-D blend reagent for patient testing on July 11, 2019. Further interview confirmed the laboratory did not have a procedure or the manufacturer's instructions for use of the reagent.	{D5401}		
{D5409} 510M	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in §493.1105(a)(2). This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and interview with the clinic director, the laboratory has not documented dates of	{D5409}		12/7/20

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{D5409}	Continued From page 2 discontinuation on procedures that are not in use. Findings include: 1. Review of the laboratory procedure manual showed the manual includes procedures for the ELDONCARD RhD test cards and Ortho Anti-D reagent. Neither procedure shows a discontinued date or any indication that the procedure is not in use. 2. Interview with the clinic director on October 5, 2020 at 11:30 AM confirmed the laboratory only performs Rh testing with Quotient Anti-D blend and also confirmed the laboratory has not maintained the dates of discontinuance or identified the discontinued procedures as such in the procedure manual.	{D5409}		
{D6013}	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the clinic director, the laboratory director did not ensure the laboratory completed verification procedures to determine	{D6013}		12/7/20

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{D6013}	Continued From page 3 the accuracy, precision, and other pertinent performance characteristics of the Quotient Anti-D blend reagents put into use for patient testing on July 11, 2019. Findings include: 1. Review of laboratory records showed no evidence of evaluation of accuracy, precision or other characteristics of the Quotient Anti-D blend reagent prior to using it for patient testing. 2. Interview with the clinic director, staff A, on October 5, 2020 at 11:30 AM confirmed the laboratory did not evaluate accuracy and precision of the test system prior to using the Quotient Anti-D blend reagent for patient testing starting on July 11, 2019. This is a repeat deficiency previously cited on April 4, 2018.	{D6013}		