Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0888142	04/04/2018
Name of Provider or Supplier	**Street Address, City, State**	
Milwaukee Womens Medical Services	1428 North Farwell Avenue, Milwaukee, 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
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory Proficiency Testing (PT) records and interview with testing personnel, the laboratory did not retain records for two of the three PT events in 2016. Findings include: 1. Review of PT records showed no evidence of records from events 2016-2 and 2016-3. 2. Interview with testing personnel, Staff A, on April 4, 2018 at 10:00 AM confirmed all PT records were not retained for two years.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and interview with testing personnel, policies and procedures have not been established to assess employee competency. Findings include: 1. Review of the laboratory's procedure manual shows no procedure for evaluation of competency of testing personnel. 2. Interview with testing personnel, Staff A, on April 4, 2018 at 9:30 AM confirmed that a procedure has not been written for competency evaluation.
D5407	PROCEDURE MANUAL

	CFR(s): 493.1251(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: Item 1: Based on surveyor review of laboratory procedures and State Agency records, and interview with testing personnel, the current laboratory director has not approved the laboratory procedures. Findings include: 1. Review of laboratory procedures showed no evidence of review or approval by the current laboratory director, staff B. 2. Review of State Agency records show the laboratory changed the director to the current director, staff B, effective October 1, 2016. 3. Interview with testing personnel, staff A, on April 4, 2018 at 10:15 AM confirmed the procedures are not signed and dated by the current director, and the director has not documented approval of the laboratory procedures. Item 2: Based on surveyor review of the RhD (Rhesus D antigen) test records and procedures, and interview with testing personnel, the laboratory did not have an approved procedure in place before beginning patient testing with the ELDONCARD RhD test. Findings include: 1. Review of current test records showed the ELDONCARD RhD test was used for patient RhD testing performed after March 20, 2018. 2. Review of laboratory procedures showed no evidence of a procedure for ELDONCARD RhD testing. 3. Interview with testing personnel, staff A, on April 4, 2018 at 10:15 AM confirmed a procedure for ELDONCARD RhD testing had not been approved, signed and dated by the laboratory director before patient test was initiated on March 20, 2018.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and manufacturer's instructions, and interview with testing personnel, room temperature monitoring and recording was not performed since initiating testing with the ELDONCARD RhD system. Findings include: 1. Review of the manufacturer's instructions showed a required storage temperature range of 5-37 degrees Celsius for ELDONCARD test cards. 2. Review of laboratory logs showed no evidence of documentation of room temperature where the cards are stored. 3. Interview with testing personnel, Staff A, on April 4, 2018 at 11: 00 AM confirmed that monitoring of room temperature is not performed.
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 testing personnel, no verification procedures had been performed before the use of ELDONCARDS for Rh testing of patient samples. Findings include: 1. Review of laboratory records showed no evidence verification studies were performed before patient testing began with the ELDONCARD RhD test system. 2. Interview with testing personnel, Staff A, on April 4, 2018 at 10:30 AM, confirmed that no verification of accuracy or precision had been completed before testing of patient samples with the ELDONCARD RhD kit starting March 20, 2018.