Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0888142	09/24/2024
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
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on surveyor review of American Proficiency Institute (API) proficiency testing (PT) and laboratory records and interview with the Technical Consultant, two testing personnel repeated testing of two of the five proficiency samples from the first immunohematology event in 2024 while a single testing person performs patient tests once. Findings include: 1. Review of the API PT 'Attestation Statement 2024 Immunology / Immunohematology -1st Event' showed two testing personnel signed the attestation statement for each of two immunohematology samples. The document showed Staff A and B tested sample Rh-01 and Staff C and D tested sample Rh-02. 2. Review of the 'Daily Laboratory Log Sheet' from April 2, 2024, showed testing personnel A and B performed Rh testing on sample Rh-01 and testing personnel C and D performed Rh testing on sample Rh-02. 3. Interview with the Technical Consultant on September 24, 2024, at 12:30 PM confirmed a second testing person does not repeat patient testing and confirmed the laboratory performed two of the five PT samples from the first event in 2024 twice when they routinely test patient samples once. This is a repeat deficiency previously cited on May 18, 2016.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

	This CONDITION is not met as evidenced by: Based on surveyor review of laboratory procedures and records, observation in the laboratory and interview with the laboratory director, the director did not provide overall management and direction in accordance with 493.1407 of this subpart. Findings include: 1. The director did not ensure testing personnel only performed moderate complexity test systems. See D6004.
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 procedures and records, observation of reagents, and interview with the Laboratory Director, the director did not ensure the laboratory limited its testing to moderate complexity tests to comply with applicable regulations. The laboratory performed 92 of 92 patient Rh tests since March 2024 using a high complexity test system. Findings include: 1. Review of laboratory procedures showed the laboratory used ALBAclone Anti-D blend reagent for Rh patient typing since the laboratory started testing in March 2024. 2. Observation of supplies in the laboratory refrigerator on September 24, 2024, at 1:00 PM revealed an open bottle of ALBAclone Anti-D blend reagent and a box of unopened ALBAclone Anti-D blend reagent. No other reagents for Rh testing were evident in the laboratory. 3. Interview with the Laboratory Director on September 24, 2024, at 12:15 PM revealed the laboratory had used ALBAclone Anti-D blend reagent for Rh typing starting on March 7, 2024, confirmed testing with the ALBAclone Anti-D blend reagent was high complexity, and confirmed the laboratory was no longer using the ALBAclone Anti-D blend reagent for Rh tests. 4. Review of records the Technical Consultant provided by email on September 27, 2024, at 9:33 AM showed the laboratory performed 92 patient Rh tests from March through September 23, 2024.