Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0888142	04/06/2022
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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on surveyor review of American Proficiency Institute (API) proficiency testing (PT) attestation statements and daily logs and interview with the technical consultant, testing personnel did not perform proficiency tests in the same manner as patient tests for three of three immunohematology events in 2021. Findings include: 1. Review of API PT attestation statements showed two testing personnel signed the attestation statement for the same immunohematology samples for RH-03 and RH-05 for event 1 and RH-08 for event 2 in 2021. 2. Review of daily patient testing logs showed two testing personnel recorded PT results for the same immunohematology samples for RH-11 and RH-12 for event 3 in 2021. Further review of daily patient testing logs showed one testing personnel recorded results for patient tests. 3. Interview with the technical consultant on April 6, 2022 at 9:25 AM confirmed two testing personnel do not perform patient testing per specimen and did not perform the proficiency tests in the same manner as patient tests for three of three immunohematology events in 2021.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

	This STANDARD is not met as evidenced by: Based on survey review of personnel records and interview with the technical consultant, the technical consultant could not provide semiannual competency evaluation documentation for one of one new testing personnel during the first year the individual performed patient testing. Findings include: 1. Review of personnel records for staff A showed initial training performed in February 2021 and annual competency evaluation in February 2022. Further review showed no documentation of a semiannual competency evaluation. 2. Interview with the technical consultant on April 6, 2022 at 9:15 AM confirmed the technical consultant could not provide semiannual competency evaluation documentation for one of one new testing personnel during the first year the individual performed patient testing.