Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2115357	02/28/2019
Name of Provider or Supplier	**Street Address, City, State**	
Froedtert Community Hospital - New Berlin	4805 S Moorland Rd - Garden Level, New Berlin, 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
D3015	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103 A facility that provides transfusion services must meet all of the requirements of this section and document all transfusion-related activities. This STANDARD is not met as evidenced by: Based on surveyor review of transfusion records for patient three and interview with the emergency department manager (staff A), the transfusion service did not document the physician's approval for the transfusion of one unit of uncrossmatched red blood cells as required on the "Certification Record of Blood Transfusion" form. Findings include: 1. Review of the "Certification Record of Blood Transfusion" form for patient three, unit number W036318314340, showed the attending physician's signature is required on the form certifying that the patient's life would be endangered by waiting for routine compatibility studies and accepting all responsibility for the emergency transfusion. The attending physician did not sign the form. The form showed staff transfused the unit to patient one starting at 1:00 AM on December 12, 2018. 2. Interview with the emergency department manager (staff A) on February 28, 2019 at 11:45 AM confirmed the attending physician is required to sign the "Certification Record of Blood Transfusion" form and also confirmed the physician did not sign the form approving transfusion of uncrossmatched blood to patient three.
D3017	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(a) Arrangement for services. The facility must have a transfusion service agreement reviewed and approved by the responsible party(ies) that govern the procurement, transfer, and availability of blood and blood products.

	This STANDARD is not met as evidenced by: Based on surveyor observation of blood products and interview and email correspondence with the Emergency Department Manager (staff A), the emergency department does not have a transfusion service agreement with the organization that supplies blood components for transfusions in the emergency department. Findings include: 1. Observation of refrigerated storage in the emergency department on February 28, 2019 at 11:35 AM showed two type O negative red cell units available for uncrossmatched transfusion. 2. Interview with the Emergency Department Manager (staff A) on February 28, 2019 at 11:35 AM revealed the emergency department performs transfusions including crossmatched or uncrossmatched red cell, platelet, and thawed fresh frozen plasma units. 3. Email correspondence with the Emergency Department Manager (staff A) on March 12, 2019 at 3:05 PM confirmed the emergency department does not have a current transfusion services agreement with their blood component supplier.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on surveyor review of information in the RALS Data Management System and two patient test reports (patient one and two) in the electronic medical record, and interview with the technical consultant, two of two test reports did not indicate the name and address of the testing laboratory. Findings include: 1. Review of information in the RALS Data Management System revealed test results for two patients that had testing performed at this location on the i-STAT analyzer. This laboratory performed testing on patient one on February 15, 2019 and on patient two on February 19, 2019. 2. The electronic medical record test reports for patient one on February 15, 2019 and patient two on February 19, 2019 identified Community Memorial Hospital Laboratory on Town Hall Road in Menomonee Falls as the testing location on both reports. 3. Interview with the technical consultant on February 28, 2019 at 10:40 AM confirmed this laboratory performed i-STAT testing for patients one and two and confirmed the test reports did not indicate the correct name and address of the testing location.