Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0397482	11/19/2021
Name of Provider or Supplier	**Street Address, City, State**	
St Elizabeth Hospital, Inc	1506 S Oneida St, Appleton, 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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on surveyor review of manufacturer package inserts, immunohematology procedures and patient records and interview with the immunohematology technical lead, staff A, the laboratory has not met the analytical system requirements at 493. 1251 through 493.1283 in the immunohematology specialty. Findings include: 1. Manufacturer package insert for Duffy A (Fya) antigen typing was not followed by testing personnel. See D5401 2. Immunohematology procedure "Rare Typing Serum-Guidelines for Quality Control" did not include limitations for antigen typing when the direct antiglobulin test is positive during patient testing. See D5403
D5401	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. This STANDARD is not met as evidenced by:

	Based on survey review of manufacturer package inserts and patient records and interview with the immunohematology technical lead, staff A, testing personnel did not follow the "Anti-Fya (Monoclonal) Gamma-clone" package insert that was used as the patient testing procedure. Findings include: 1. Review of the "Anti-Fya (Monoclonal) Gamma-clone" package insert showed "Red blood cells having a positive direct antiglobulin test (DAT) due to coating of IgG cannot be typed by the indirect antiglobulin technique". 2. Review of patient records from patient 1 revealed the patient had a positive direct antiglobulin test (DAT) test and testing personnel performed Duffy A (Fya) antigen testing on patient 1 using an indirect antiglobulin technique. Further review of the transfusion reaction workup on November 25, 2020 revealed patient 1 had a transfusion reaction due to receiving a Fya positive unit. 3. Interview with staff A on November 19, 2021 at 12:10 PM confirmed the package insert was used as the procedure for Fya antigen typing. Further interview confirmed testing personnel did not follow the "Anti-Fya (Monoclonal) Gamma-clone" package insert that was used as the patient testing procedure and patient 1 had a transfusion reaction due to receiving a Fya positive unit.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on survey review of manufacturer package inserts and immunohematology procedures, and interview with the immunohematology technical lead, staff A, the immunohematology procedure for antigen typing on patients did not include limitations from the package inserts. Findings include: 1. Review of the "Anti-Fya (Monoclonal) Gamma-clone" package insert limitations showed "Red blood cells having a positive direct antiglobulin test (DAT) due to coating of IgG cannot be typed by the indirect antiglobulin technique". 2. Review of "Rare Typing Serum-Guidelines for Quality Control" procedure revealed the laboratory did not include limitations for antigen typing when the direct antiglobulin test (DAT) is positive during patient testing. 3. Interview with staff A on November 19, 2021 at 11:53 AM confirmed the immunohematology procedures for antigen typing on patients did not include limitations from the manufacturer package insert.