Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0396909	07/13/2022
Name of Provider or Supplier	**Street Address, City, State**	
Tri-County Memorial Hospital	18601 Lincoln St, Whitehall, 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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor review of immunohematology and general laboratory records and interview with the general supervisor, the laboratory MTS (Micro Typing System) diluent 2 available for blood bank testing was expired ten of the thirty days in September 2021. Testing personnel performed testing on three patients during the ten days the reagent was expired. Findings include: 1. Review of the "Blood Bank Gel Card Quality Control Record" from September 2021 showed testing personnel put MTS diluent 2 lot number MD143 into use on July 31, 2021; the diluent expiration date was September 9, 2021. The record also showed testing personnel put a new lot, MD152, into use on September 20, 2021. The general supervisor initialed and dated the record on October 7, 2021, the record showed no sign the general supervisor found the expired reagent was available for use during the record review. 2. Review of the "Blood Bank Worksheet" in use from September 3 through 23, 2021 showed testing personnel performed patient testing on September 13, 17 and 19 when the expired MTS diluent 2 was available for use. 3. Review of the "Overnight Shift" checklist showed testing personnel checked the expiration dates of Blood Bank cards, diluent, and reagents on September 12 and 19, 2021. 4. Interview with the general supervisor on July 13, 2022 at 10:00 AM confirmed the MTS diluent 2 was available for testing of three patients after the reagent had expired on September 9, 2021. This is a repeat deficiency previously cited on December 22, 2020.
D5553	IMMUNOHEMATOLOGY CFR(s): 493.1271(b)(f)

	(b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b). (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures, transfusion records, and interview with the general supervisor, testing personnel did not follow laboratory procedures and did not obtain the signature of the physician ordering an emergency blood release for transfusion for one of one patient reviewed. Findings include 1. Review of the procedure, "Emergency Blood Release, Lab-8677", showed the 'Procedural Notes' section included the following, "When blood is released before pretransfusion testing is complete, the records must contain a signed statement from the requesting physician indicating that the clinical situation was sufficiently urgent to require release of blood". The 'Limitations' section stated, "Ideally, the "Emergency Transfusion Request" form should be signed before the unit is released if the crossmatch has not been completed. In the event that it is impossible for the physician to sign immediately, the Emergency Transfusion Request MUST be signed within 24 hours." 2. Review of transfusion records for patient 1 showed the physician ordered and transfused one unit of blood as an emergency transfusion on June 5, 2022. No "Emergency Transfusion Request" form was with the records. 3. Interview with the general supervisor on July 13, 2022 at 10:00 AM confirmed testing personnel did not ensure completion of the "Emergency Transfusion Request" form for the transfusion for patient 1 on June 5, 2022 and the laboratory had not obtained the physician's signature as required in 21 CFR 606.160(b)(3)(v).
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on surveyor review of procedures, quality control (QC) records, and instrument logs and interview with the general supervisor, testing personnel did not test hematology controls each morning on twelve of sixty-one days between October 13 and December 13, 2021 as required in the procedure. Findings include: 1. Procedure "Sysmex XN-450/XN550 Complete Blood Count and Parameters - Whole Blood" stated, "XN-L CHECK controls levels 1, 2, and 3 will be run each morning before reporting patient results." 2. Review of QC records on the Sysmex Insight Raw Data Report for lot 1267 from October 13 to December 13, 2021 showed QC material was not tested in the morning but was tested in the afternoon or evening on November 18, 19, 20, 21, 29 and 30, and December 1, 2, 3, 4, and 5. The record showed controls were tested at 4:15 PM on December 5, 2021 and no controls were tested on December 6, 2021. 3. Review of instrument logs showed five patient samples were tested on December 6, 2021 between 1:39 AM and 8:16 AM. 4. Interview with the

	general supervisor on July 13, 2022 at 11:30 AM confirmed testing personnel did not follow the procedure to test hematology controls in the morning prior to reporting patient results.