Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	20D0089119	01/18/2024
Name of Provider or Supplier	**Street Address, City, State**	
Rumford Hospital	420 Franklin Street, Rumford, ME	

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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on record review and interview with the Technical Supervisor (TS), the laboratory failed to verify testing accuracy when the proficiency testing program did not evaluate the submitted results for one of three Coagulation events and one of three Hematology events. Findings include: 1. Record review on 01/16/2024 of 2023 proficiency testing records revealed the laboratory failed to verify the accuracy of testing when the proficiency testing program did not evaluate the submitted results for one of three Coagulation events and one of three Hematology events a. Coagulation CGL-A 2023 Event - five of five results for "PT, qual" (CGL-01, CGL-02, CGL-03, CGL-04, CGL-05) were not graded by the proficiency testing program. Under "Your Grade" stated, "See Note [26]" and "Review participant summary for comparative results and document performance accordingly." b. Hematology FH9-B 2023 Event - five of five results for "Blood Cell ID" (BCP-16, BCP-17, BCP-18, BCP-19, BCP-20) were not graded by the proficiency testing program. Under "Your Grade" stated, "See Note [26]" and "Review participant summary for comparative results and document performance accordingly." 2. Record review on 01/16/2024 of 2023 proficiency testing records revealed no evidence the laboratory documented a self-evaluation of non-graded results. 3. Interview with the TS on 01/16/2024 at 03:00 PM confirmed the findings above.
D5559	IMMUNOHEMATOLOGY

	CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (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 record review, written laboratory policy, and interview with the Technical Supervisor (TS) and Director of Laboratory Services, the facility failed to ensure that written policies provided safety for individuals being transfused for four of five patients reviewed. Findings include: 1. Interview with the Director of Laboratory Services on 1/17/2024 at 02:45 PM, confirmed the laboratory stored units of Packed Red Blood Cells (PRBCs) in the blood bank refrigerator, and the units were used for patient transfusions. 2. Record review on 01/17/2024 of the hospital policy titled, "Administration of Blood Components" under "Documentation" stated the following: a. "2. Document vital signs at following intervals: prior to and after the start of the transfusion, 5 minutes, 15 minutes, every 30 minutes thereafter if patient is stable, and 30 minutes post completion of the transfusion. (Vital sign timing should begin when the blood product begins to infuse into the patient.).". 3. Record review on 01/18/2024 of five patients transfused between 12/21/2023 through 01/11/2024 revealed the policy was not followed for four of five patients as follows: a. Patient #725363 - Transfused with one unit of O positive (unit# W037923210529) PRBC on 12/21/2023 revealed vitals not documented every 30 minutes. Vitals not documented between 05: 10 PM and 06:08 PM; 06:08 PM and 07:00 PM; 07:00 PM and 07:55 PM. b. Patient #1009112 - Transfused with one unit of O positive (unit# W037923236086) PRBC on 12/26/2023 revealed vitals not documented 30 minutes post completion of the transfusion. Vitals not documented between 01:00 PM (stop time) and 01:45 PM. c. Patient #1018267 - Transfused with one unit of O positive (unit# W037923236086) PRBC on 12/26/2023 revealed vitals not documented 30 minutes post completion of the transfusion. Vitals not documented after 01:25 PM (stop time). d. Patient #99413 - Transfused with one unit of O positive (unit #W051723630105) PRBC on 01/11/2024 revealed vitals not taken five minutes after the start of the transfusion. Vitals not documented between 10:25 AM (start time) and 10:33 AM. 4. Interview with the TS on 01/18/2024 at 10:20 AM confirmed the findings above. 5. The laboratory performs approximately 3,377 Immunohematology tests per year.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by:

	Based on record review and staff interview, the Technical Consultant (TC) failed to evaluate the competency of all Testing Personnel (TP) to perform moderate complexity testing. Findings include: 1. Record review on 1/17/2024 of the laboratory's 2023 TP competency records revealed 7 of 8 moderate complexity TP did not have complete competency performed by the TC. 2. Staff interview with the TC on 1/17/2024 at 2:00 PM confirmed the above findings. 3. The laboratory performs approximately 230,000 Moderate Complexity test per year.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on record review and staff interview, the Technical Consultant (TC) failed to evaluate the monthly Unity quality control records. Findings include: 1. Record review on 1/17/2024 of the laboratory's 2023 Unity monthly evaluation records revealed no TC review. 2. Staff interview with the TC on 1/17/2024 at 2:00 PM confirmed the above findings. 3. The laboratory performs approximately 230,000 Moderate Complexity test per year.