Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 20D0090507	(X3) Date Survey Completed 10/30/2024
Name of Provider or Supplier Redington Fairview General Hospital	**Street Address, City, State** 46 Fairview Ave, Skowhegan, 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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of the laboratory's College of American Pathologists (CAP) Immunohematology proficiency testing (PT) records (2023 1st, 2nd, and 3rd events, and 2024 1st and 2nd events), and confirmed in an interview with the Technical Supervisor (TS) - 1 according to the Centers for Medicare and Medicaid Services (CMS)-209 Form, the laboratory failed to have the attestation statement provided by the PT program signed by the laboratory director for 4 of 5 PT events. Findings included: a. A review of the laboratory's College of American Pathologists (CAP) Immunohematology proficiency testing records (2023 1st, 2nd, and 3rd events, and 2024 1st and 2nd events) revealed the following records were not maintained: 1. CAP Immunohematology event for November 21, 2023, Kit# 3615349410397 did not include the laboratory director's signature on the attestation form. 2. CAP Immunohematology event 'DAT-B 2023' did not include the laboratory director's signature on the attestation form. 3. CAP Immunohematology event for September 27, 2023, Kit# 3615475301232, did not include the laboratory director's signature on the attestation form. 4. CAP Immunohematology event for May 14, 2024, Kit#

	3728474280386, did not include the laboratory director's signature on the attestation form. 5. CAP Immunohematology event 'HBF-A 2024' did not include the laboratory director's signature on the attestation form. 6. CAP Immunohematology event for June 25, 2024, Kit # 3728507990995, did not include the laboratory director's signature on the attestation form. b. In an interview on 10/29/24 at 1:55 pm, TS-1 confirmed the Laboratory director had not signed the proficiency testing attestation forms.
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on laboratory personnel interview and immunohematology patient test record and test requisition record review on October 29, 2024 at 10:30 am, the laboratory failed to have a written or electronic request for a patient direct antiglobulin testing (DAT) from an authorized person for which the laboratory performed and reported on March 7, 2024. Findings included: a. In the afternoon of March 7, 2024, the laboratory received an electronic request and accompanying patient (patient number RF0000166051) specimen for a DAT. b. The laboratory performed and reported a DAT test result on a specimen from patient number RF0000166051 that was received by the laboratory in the morning of March 7, 2024, but not on the specimen received in the afternoon of March 7, 2024. c. The laboratory maintained no written or electronic request for the patient DAT test result performed and reported on the patient specimen received in the morning of March 7, 2024. d. According to laboratory records, the laboratory performed approximately 3,557 patient immunohematology tests annually.
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: I. Based on direct observation, review of temperature records, test volume, laboratory microbiology policies and procedures, and interview with Technical Supervisor (TS) -1 according to the Centers for Medicare and Medicaid (CMS) - 209 form, the laboratory failed to follow its own policy of maintaining proper room temperatures while performing 38 of 38 fungal cultures. Findings included: a. During a tour of the laboratory on 10/30/2024 at 3:27 pm, the Mycology section within the Microbiology room of the laboratory showed a room temperature reading documented of 21 degrees Celsius. b. A review of the laboratory's temperature records titled "Redington Fairview General Hospital Laboratory Microbiology Department Temperature Record for Mycology" showed a room temperature range of 18-22 degrees Celsius. c. Review of the laboratory's policy titled "Redington Fairview General Hospital Laboratory Microbiology Department Fungus Culture", stated the following requirements on page 2 of 3: "Incubate at room temperature 22-26 degrees Celsius for 4 weeks before

	signing out as negative ..." d. A review of the laboratory's test volume showed 38 fungal cultures performed in 2023 and 2024. e. In an interview on 10/30/2024 at 3:30 pm, the TS-1 corroborated the temperature findings. II. Based on direct observation, test volume, laboratory policy, and interview with TS-1 according to the CMS-209 form, the laboratory failed to follow its own policy of maintaining proper room temperature for 1 of 1 blood bank test methodology (Direct Antiglobulin Test). Findings included: a. During a tour of the laboratory on 10/29/2024 at 12:18 pm, the blood bank section of the laboratory was observed with a temperature range of 15-25 degrees Celsius. b. A review of the laboratory's test volume showed 61 Direct Coombs tests (Direct Antiglobulin Test) performed in 2023 and 2024. c. A review of the laboratory's policy titled "Redington Fairview General Hospital Direct Antiglobulin Test using MTS Anti-IgG and MTS Buffered Gel Card with Anti-C3b,-C3d" stated the following requirements on page 3 of 7: "Patient Test Procedure: Bring samples and reagents to room temperature (18-25 degrees Celsius)." d. In an interview on 10/30/2024 at 3:30 pm, the TS-1 corroborated the temperature findings. III. Based on direct observation, test volume, laboratory policy, temperature records, and interview with Technical Supervisor (TS) -1 according to the CMS-209 form, the laboratory failed to follow its own policy of maintaining proper incubator temperatures during testing for 4 of 303 days. Findings included: a. During a tour of the laboratory on 10/30/2024 at 10:23 am, 3 incubators were observed in the microbiology section of the laboratory. b. A review of the laboratory's policy titled "Redington Fairview General Hospital Microbiology Department Stool Culture for Enteric Pathogens" stated the following: "X. Quality Control: The temperature of the 42 degree Celsius incubator used to incubate the Campy plates is recorded daily to ensure there are appropriate incubation conditions to support the growth of Campylobacter," and "XII. Procedure: 6. Place the Campylobacter plate into a pouch with a Campy Pak and incubate at 42 degrees Celsius for 48 hours prior to opening the pouch." c.. A review of the laboratory's temperature records for the incubator thermometer SN#160793426 from January 1, 2024 to October 30, 2024 revealed the following dates and temperatures, not in accordance with the laboratory's policy: 2/24 /24, 41 degrees Celsius 2/29/24, 41 degrees Celsius 5/31/24, 41 degrees Celsius 8/2 /24, 40 degrees Celsius d. In an interview on 10/30/2024 at 10:41 am, the TS-1 corroborated the temperature findings.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: I. Based on observation, manufacturer's instructions, review of temperature records, and interview with Testing Personnel (TP) - 7 according to the CMS-209 form, the laboratory failed to follow manufacturer's instructions for storing 11 of 11 Remel 5% Sheep Blood Agar (SBA) plates, 11 of 11 Remel MacConkey Agar Plates, and 2 of 2 Microgenics Corporation MAS Urinalysis (UA) Control bottles. Findings included: a. In direct observation on 10/29/2024 at 12:18 pm within the UA/Chemistry area of the laboratory, the following was observed: 1. 11 Remel 5% SBA Plates, Lot 173092, expiration date 2024-11-18; manufacturer storage temperature requirements 2-8 degrees Celsius. 2. 11 Remel MacConkey Plates, Lot 170125, expiration date 2024-11-

	21, manufacturer storage temperature requirements 2-8 degrees Celsius. 3. 1 Microgenics Corporation MAS UA Control bottle, Lot UB1526021A, expiration date 2024-11-26, manufacturer storage temperature requirements 2-8 degrees Celsius. 4. 1 Microgenics Corporations MAS UA Control bottle, Lot UB1525022B, expiration date 2024-11-23, manufacturer storage temperature requirements 2-8 degrees Celsius. b. Review of the temperature records titled "Redington Fairview General Hospital Laboratory Department Daily Temperature Chart" showed an acceptable room temperature range of 15-40 degrees Celsius. c. In an interview on 10/29/2024 at 3:22 pm, TP-7 confirmed the temperature and manufacturer instructions findings. II. Based on observation, manufacturer's instructions, review of freezer temperature records, and interview with TS-2, the laboratory failed to follow manufacturer's instructions for storing 30 of 30 Becton Dickinson and Company (BD) BBL Trypticase Soy Broth with 20% Glycerol tubes. Findings included: a. During a tour of the laboratory on 10 /30/2024 at 10:51 am, the following reagents were observed not stored in accordance with manufacturer's instructions within Chemistry Freezer #2: 30 BD BBL Trypticase Soy Broth with 20% Glycerol Tubes, Lot 297337, manufacturer storage requirements 2-25 degrees Celsius. b. A review of the list of freezers and temperature ranges showed the temperature range for Chemistry Freezer #2 set to -30.2 to -24.1 degrees Celsius. c. In an interview on 10/30/2024 at 11:03 am, the TS-2 corroborated that the tubes were stored not in accordance with the manufacturer's instructions on the tube.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on direct observation, manufacturer instructions, and interview with the Technical Supervisor (TS) -1 according to the Centers for Medicare and Medicaid (CMS) - 209, the laboratory failed to monitor and document the room temperature for 1 of 1 storage rooms in which temperature dependent supplies were stored. Findings Included: a. During a tour of the laboratory on 10/29/2024 at 12:33 pm, the following laboratory supplies were observed in the phlebotomy storage room without temperature monitoring: 1. 46 Becton, Dickinson and Company (BD) Bactec Standard Anaerobic Culture Vials, Lot 4199110, expiration date 2025-07-22; manufacturer storage temperature requirements 2-25 degrees Celsius. 2. 17 Bactec Peds Plus/F Culture Vials, Lot 4185830, expiration date 2025-07-07; manufacturer storage temperature requirements 2-25 degrees Celsius. 3. 39 packages of Greiner bio-one vacuette Lithium Heparin tubes, Lot B240233G, expiration date 2025-05-02; manufacturer storage temperature requirements 4-25 degrees Celsius. 4. 34 packages of Greiner bio-one vacuette Sodium citrate tubes, Lot B24073EC, expiration date 2025-07-02; manufacturer storage temperature requirements 4-25 degrees Celsius. b. During an interview on 10/29/2024 at 12:50 pm, the TS-1 corroborated the findings that room temperature was not being monitored and recorded in the phlebotomy supply storage room.

D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on laboratory personnel interview and hematology and urinalysis microscope maintenance record review on October 29, 2024 at 2:30 pm, the laboratory failed to establish a written microscope maintenance protocol that ensured microscope performance necessary for accurate and reliable patient test results and test results reporting. Findings included: a. It was the practice of the laboratory to use microscopes to examine and report patient urine microscopy/sediment test results and patient manual white blood cell differentials. b. According to laboratory personnel, even though the laboratory performed annual maintenance for each microscope in use, the laboratory maintained no written policies and procedures establishing any (daily, weekly, monthly, and/or annual) microscope maintenance protocols. c. According to laboratory personnel, the laboratory performed and reported approximately 100 patient urine microscopy examinations weekly, and approximately 400 patient manual white blood cell differentials daily.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on laboratory personnel interviews and routine chemistry, endocrinology, and toxicology quality control documentation record review on October 29, 2024 at 11:30 am, the laboratory failed to document all quality control procedure performed including documentation establishing the statistical parameters, specifically standard deviations, for routine chemistry, endocrinology, and toxicology quality control materials in use to monitor patient specimen testing. Findings included: a. It was the practice of the laboratory to test patient routine chemistry, endocrinology, and toxicology patient specimens using the Vitros XT 7600 and Vitros XT 3400 test systems. To monitor patient testing using these test systems, the laboratory used quality control materials for which the laboratory established statistical parameters (i. e., mean and standard deviation) used to define the laboratory's quality control materials' criteria for acceptability. b. As confirmed by laboratory personnel, the laboratory maintained no documentation to support the standard deviations used to define the laboratory's criteria for acceptability for all its routine chemistry, endocrinology, and toxicology quality control materials in use. c. According to laboratory records, the laboratory performed approximately 330,000 patient routine chemistry, endocrinology, and toxicology tests annually.

D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on interview with Technical Consultant (TC) and chemistry policies and procedures record review on March 29, 2024 at 11:00 am, the laboratory director (LD) failed to ensure that the supplementary procedure manual was approved prior to testing patient specimens in the specialty of Chemistry. Findings include: a. Record review of the laboratory's chemistry supplementary testing manual on March 29, 2024 revealed no signature of approval by the LD. b. Interview with the TC on March 29, 2024 at 11:00 am confirmed these findings. c. According to laboratory records, the laboratory performs approximately 330,000 patient tests annually in the specialty of Chemistry.