Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 20D0088760	(X3) Date Survey Completed 08/21/2024
Name of Provider or Supplier Coastal Women's Healthcare	**Street Address, City, State** 71 Us Route 1, Suite A, Scarborough, 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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory's quality program failed to monitor, identify, and correct problems in the general laboratory systems. The findings include: 1. Failure to monitor, identify required policy procedural requirements. Refer 6094. 2. Failure to identify maintenance documentation errors. Refer 5429. 3. Failure to monitor, identify, correct irregularities in reference ranges. Refer 5407.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on record review and interview with the general supervisor #1 (GS1), it was determined that reference ranges in the laboratory's procedure did not correlate with reference ranges on the final patient test report for Chemistry and Hematology. Findings include: 1. Comparison on 8/21/24 of final patient test report's reference ranges with the laboratory's "Procedure In-House Test List with Reference Ranges" policy revealed the following did not match: a. Glucose (GTT) 3hr Final report: 65-

	139 mg/dL Policy: 65-140 mg/dL b. Glucose 1hr Final report: 65.00-135.49 mg/dL Policy: No reference range noted c. Auto diff Lymphocytes % Final report: 20.0-48.0 % Policy: 20-50 % d. Auto diff Basophils % Final report: 0.0-2.0 % Policy: 0.0-3.5 % 2. Staff interview with GS1 on 8/1/24 at 11:30 AM confirmed the findings above. 3. The laboratory performs 12,470 tests annually under the specialty of Chemistry, and 44,846 tests annually under the specialty of Hematology.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with general supervisor #1 (GS1), the laboratory failed to document routine maintenance on the Sysmex XN 430 hematology analyzer and Clinitek chemistry analyzer. Findings include: 1. Record review of the laboratory analyzer maintenance logs on 8/21/24 revealed: a. Sysmex XN 430 analyzer to be missing 14 of 88 weeks documentation of weekly maintenance. b. Clinitek chemistry analyzer to be missing 9 of 88 weeks documentation of weekly maintenance. c. The logs were reviewed/signed by the laboratory manager, spectrum technologist, and the laboratory director. 2. Record review of the laboratory "Quality Plan" on 8/21/24 revealed the following: "...specific objectives... Implantation and monitoring of quality control, calibration, and maintenance programs", and "The Quality Management group of the Laboratory oversees quality improvements activities of the laboratory... The group recommends policy and meets monthly to monitor progress...". 3. Interview with GS1 on 8/21/24 at 10:00am confirmed the above findings. 4. The laboratory performs 44,846 tests per year under the specialty of Hematology, and 12,470 tests per year under the specialty of Chemistry.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and interview with the general supervisor #1 (GS1), the laboratory director failed to document the approval of the individualized quality control plan (IQCP) in the specialty of microbiology. Findings include: 1. Record review of the laboratory's IQCP on 8/21/24 revealed the policy was not approved or documented an annual risk assessment review by the laboratory director since 2022. 2. Record review of the laboratory IQCP policy for HIV-1/2 Ag/Ab combo test on 8/21 /24 revealed the following: "The effectiveness of the QCP will be monitored through the laboratory's Quality Assessment program... Problems will be reported to the Laboratory Supervisor and necessary actions will be taken." 3. Record review of the "Laboratory Quality Plan on 8/21/24 revealed the following: "... objectives of the quality plan... Periodic review of policies and procedures... Implementation and

	monitoring of quality control, calibration, and maintenance programs." 4. Staff interview with GS1 on 8/24/24 at 11:00 AM confirmed the above findings. 5. The laboratory performs 10,922 compliance level tests per year in the specialty of Microbiology.