Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	20D0088760	08/31/2022
Name of Provider or Supplier	**Street Address, City, State**	
Coastal Women's Healthcare	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
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and interview with Technical Supervisor #1 (TS1), the laboratory director failed to ensure a policy for the competency of Technical Supervisors. Findings include: 1. Record review of the laboratory's procedure manual on 8/31/2022 revealed no documentation specifying Technical Supervisor competency. 2. Staff interview with (TS1) on 8/31/2022 at 10:00 AM confirmed the lab manual did not have a written policy for the Technical Supervisor's competency and that no Technical Supervisor competency has been performed. 3. The laboratory performs 50,699 compliance level tests per year under the specialties of Microbiology, Diagnostic Immunology, Chemistry, Hematology, and Immunohematology.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each

	consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on record review and interview with Technical Supervisor #1 (TS1), the laboratory director failed to specify, in writing, the responsibilities and duties of each consultant and each supervisor prior to testing. Findings include: 1. Record review of the laboratory's procedure manual on 8/31/2022 revealed no documentation specifying the duties of the Technical Consultant, Technical Supervisor, and General Supervisor. 2. Staff interview with (TS1) on 8/31/2022 at 9:00 AM confirmed the lab manual did not have a written responsibilities section outlining the above positions. 3. The laboratory performs 50,699 compliance level tests per year under the specialties of Microbiology, Diagnostic Immunology, Chemistry, Hematology, and Immunohematology.