Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	20D0089859	06/07/2024
Name of Provider or Supplier	**Street Address, City, State**	
Calais Community Hospital	24 Hospital Lane, Calais, 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
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 technical consultant 1 (TC1), the laboratory failed to document routine weekly maintenance on the Cephied GeneXpert Microbiology test system. Findings include: 1. Record review of the CMS form 116 on 6/5/2024 revealed the laboratory performs Strep A, T. Vaginalis, C. Difficile/EPI, Gonorrhea, and Chlamydia testing on the Cepheid GeneXpert. 2. Record review of the GeneXpert maintenance logs on 6/5/2024 revealed 5 out of 17 months reviewed to be missing a weekly maintenance log entry. 3. Interview with TC1 on 6/6/2024 at 9: 00am confirmed the above findings. 4. The laboratory perform 2'557 tests annually in the specialty of Microbiology. .
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on staff interviews and record review the laboratory failed to follow their own Quality Assurance Program policy concerning corrective action documentation.

	Findings include: 1. Record review conducted on 05/6/2024 of the Sysmex XN-1000 Hematology Manufacturer quality Control Review Report revealed a test system negative bias issue the months of January 2023 - March 2023. The corrective action reports were signed by the Technical Consultant 1 (laboratory manager), Technical Consultant 2, and "Dahl Chase Consultant". 2. Record review of the laboratory Quality Assurance Program on 6/6/2024 revealed: "All Quality reviews and activities are documented. This documentation should include: ...6. Signature of the laboratory manager and medical laboratory director." 3. Interview with TC1 and the Dahl Chase Consultant on 6/6/2024 at 9:00am confirmed the above findings. 4. The laboratory performs 60'215 tests annually under the specialty of Hematology. .
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory Director (LD) failed to provide a Quality Program that assures compliance with regulations. Findings include: 1. Record review of the laboratory Quality Assurance Program on 6/6/2024 revealed a 4-page document including header and digital signature page with a general outline of Quality Assurance procedures that were not specific or detailed the specialties performed by the laboratory. 2. The LD receives a report each month of quality activities that he is not required to document acknowledgement of review. Refer to D5791. 3. The LD was unaware that quality maintenance activities undocumented in the laboratory. Refer to D5429. 4. Interview with TC1 and the Dahl Chase consultant on 6/7/2024 at 8:30am confirmed the above findings. 5. The laboratory performs 205'325 tests annually under the specialties of Microbiology, Diagnostic Immunology, Chemistry, Hematology, and Immunohematology. .