

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 20D0089859	(X3) Date Survey Completed 09/25/2026
Name of Provider or Supplier Calais Community Hospital	Street Address, City, State 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
D2173	COMPATIBILITY TESTING CFR(s): 493.863(a) (a) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) data report (CASPER Report 096D), PT graded results from the American Proficiency Institute (API) and interview with General Supervisor #1 (GS1) the laboratory failed to attain a score of at least 100% for the regulated analyte compatibility testing in the specialty of Immunohematology. Findings include: 1. Record review on 9/22/2026 of the CASPER Report 096D, revealed, the laboratory received an unsatisfactory PT score of 60% for the regulated analyte compatibility testing for 2026 Event 2. 2. Record review on 9/22/2026 of the laboratory's 2026 API PT records revealed, unsatisfactory PT score of 60% for the regulated analyte compatibility testing for 2026 Event 2. 3. Staff interview on 9/22 /2026 at 12:15 PM with GS1 confirmed the above findings. 4. The laboratory performs 65 compatibility tests annually in the specialty of Immunohematology.
D2179	COMPATIBILITY TESTING CFR(s): 493.863(d) (d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

This STANDARD is not met as evidenced by:
Based on record review and staff interview with General Supervisor #1 (GS1), the laboratory failed to investigate and document corrective action for an unsatisfactory proficiency testing (PT) result obtained from the American Proficiency Institute (API) for the regulated analyte compatibility testing in the specialty of Immunohematology. Findings Include: 1. Record review on 9/22/2026 of the CASPER Report 096D, revealed, the laboratory received an unsatisfactory PT score of 60% for the regulated analyte compatibility testing for 2026 Event 2. 2. Record review on 9/22/2026 of the laboratory's 2026 API PT records revealed: a. The laboratory did not have graded PT results from API for the above PT event. b. The laboratory had no documentation of an investigation into the unsatisfactory PT result or corrective action taken to identify and to correct the cause of the PT failure. 3. Record review on 9/22/2026 of the API '2026 API PT Schedule' revealed that Immunohematology API results for 2026 Event 2 were available online on 9/1/2026. 4. During an interview on 9/22/2026 at 12:15 PM, GS1: a. GS1 confirmed the above findings. b. GS1 stated, "The hardcopy of the results have not been received from API as of 9/22/2026. I usually wait until the hard copy comes through the mail to review and investigate PT results. I am not sure why I haven't received them yet." c. At the surveyor's request, GS1 checked the mail for the PT results. d. GS1 located the PT results in the mailbox outside of the original mailing envelope. The original mailing envelope could not be located. GS1 stated, "The results possibly went to another department and that is why it was delayed." 5. The laboratory performs 65 compatibility tests annually in the specialty of Immunohematology.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
Based on observation of the contents of the laboratory refrigerator and interview with General Supervisor #1 (GS1) the laboratory failed to label calibrators with the revised expiration date following initial opening in the subspecialty of Routine Chemistry. Findings include: 1. Surveyor observation on 9/22/2026 at 1:00 PM of the contents of the laboratory refrigerator revealed: a. Folate calibrators lot number 633434 with an open date written on the box of 7/23/26 documented on the box. b. Access B-Type Natriuretic Peptide (BNP) calibrators lot number 539234 with an open date of 8/31/26 documented on the box. c. The above calibrators did not have the revised expiration date after opening written on the label. 2. Record review on 9/22/2026 of the Folate calibrator package insert revealed, "Vial is stable at 2 to 10 degrees Celsius for 90 days after initial use." 3. Record review on 9/22/2026 of the BNP calibrator package insert revealed, "Vial is stable at 2 to 10 degrees Celsius for 30 days after initial use or when removed from frozen storage." 4. During an interview with GS1 on 9/22/26 at 1:00 PM, GS1 confirmed that the revised expiration date following opening had not been documented on the calibrator labels. 5. The laboratory performs 128,485 tests annually in the subspecialty of Routine Chemistry.