

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 20D0089891	(X3) Date Survey Completed 04/11/2023
Name of Provider or Supplier Down East Community Hospital	Street Address, City, State 11 Hospital Drive, Machias, 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	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with Technical Supervisor #1 (TS1), the laboratory failed to document routine maintenance and function checks on the Cobas/Roche e411 analyzer. Findings include: 1. Record review of the testing list on 4/11/2023 at 10:00 AM revealed the laboratory performs Chemistry testing on the Cobas/Roche e411. 2. Record review of the laboratory e411 maintenance logs from January 2022 - March 2023 on 4/11/2023 revealed the weekly maintenance, "Clean incubator and aspiration station" and "Clean sipper probe", not documented 6 times. 3. Interview with TS1 on 4/11/2023 at 10:AM revealed that the testing personnel had failed to document the weekly maintenance. 4. The laboratory performs 248,797 tests per year under the Chemistry specialty.</p>
D6128	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on record review and staff interview, the laboratory failed to evaluate the competency of all testing personnel (TP). Findings include: 1. Record review on 4/11/2023 of the laboratory's 2022 and 2023 TP competency records revealed 2 of 8 TP missing an annual competency. 2. Staff interview with the Technical Supervisor on 4/11/2023 at 9:30AM confirmed the above findings. 3. The laboratory performs 280,675 test annually.