

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 20D2277679	(X3) Date Survey Completed 12/19/2023
Name of Provider or Supplier Quest Diagnostics Llc	Street Address, City, State 1 Cumberland Pl, Bangor, 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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory manager, the laboratory failed to ensure the laboratory director or designee signed the proficiency testing attestation statement for one of six events. Findings include: 1. Record review on 12 /18/2023 of 2023 proficiency testing records revealed the laboratory failed to ensure the proficiency testing attestation statement for 2023 Y-B Sex Hormones was signed by the laboratory director or designee. 2. Interview with the laboratory director on 12 /18/2023 at 02:12 PM confirmed the above findings.</p>
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score</p>

for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

Based on record review and interview with the laboratory manager, the laboratory failed to verify the accuracy of testing when the proficiency testing program did not evaluate the submitted results for one of six events. Findings include: 1. Record review on 12/18/2023 of 2023 proficiency testing records revealed the laboratory failed to verify the accuracy of testing when the proficiency testing program did not evaluate the submitted results for one of six events. a. Cardiac Markers CAR-C 2023 Event - one of five results (CK-MB HCR-11) was not graded by the proficiency testing program. Under "Your Grade" stated, "See Note [20]" and "Document that the laboratory performed a self-evaluation using the data presented in the participant summary and compared its results to a similar method, all method, all participant statistics, or data tables for groups of 3-9 laboratories, if provided.". b. Cardiac Markers CAR-C 2023 Event - one of five results (Troponin I HCR-13) was not graded by the proficiency testing program. Under "Your Grade" stated, "See Note [28]" and "Document that the laboratory performed a self-evaluation and compared its results to the proper statistics supplied in the participant summary.". 2. Record review on 12/18/2023 revealed no evidence the laboratory documented a self-evaluation of non-graded results. 3. Interview with the laboratory manager on 12/18/23 at 02:10 PM confirmed the findings above.

D5413

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

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on record review, manufacturer's instructions, humidity records, and interview with the laboratory manager, the laboratory failed to ensure the humidity was maintained as required by the manufacturer for one of four months. Findings include: 1. Interview with the laboratory manager on 12/18/23 at 10:45 AM, confirmed the laboratory performed routine chemistry testing using the Beckman Coulter AU480 analyzer. 2. On 12/19/2023, a review of the manufacturer's instructions, "Installation Environment" page 4-3 required a relative humidity of 30 to 80%. 3. Record review on 12/19/2023 of humidity records from August 2023 through November 2023, revealed the laboratory failed to ensure the humidity was maintained as required by the manufacturer for one of four months as follows: a. November 2023 - 10 out of 30 humidity readings were documented as less than 30% (days 9,10,13,14,15,16,17,20,29,30). 4. Interview with the laboratory manager on 11/02/23 at 03:50 PM, confirmed the findings above.