Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0645258	08/12/2025
Name of Provider or Supplier	**Street Address, City, State**	
Quest Diagnostics Clinical Laboratories Inc	701 N 14th St Ste 2, Leesburg, FL	

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
D0000	An announced CLIA recertification survey was conducted at Quest Diagnostic Laboratories Inc on July 16 , 2025 to August 12, 2025. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) (b)The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on interview, review of College of American Pathologists (CAP) Proficiency Testing (PT) records and the procedure manual, the laboratory failed to run proficiency testing samples for hematology in the same manner as it runs patients for two (2024 3rd, 2025 1st) of five (2024 1st, 2nd, 3rd, 2025 1st, 2nd) events for hematology, two (2024 3rd, 2025 1st) of five (2024 1st, 2nd, 3rd, 2025 1st, 2nd) events for coagulation, two (2024 3rd, 2025 2nd) of five (2024 1st, 2nd, 3rd, 2025 1st, 2nd) events for chemistry, and one (2025 2nd) of five (2024 1st, 2nd, 3rd, 2025 1st, 2nd) events for human chorionic gonadotropin (hCG). Findings: 1. Review of the API Attestation Statement read, "We, the undersigned, recognizing that some special handling may be required due to the nature of proficiency testing (PT) materials, have as closely as is practical, perform the analysis on these specimens in the same manner as regular patient specimens." Review of the attestations showed all attestations were

	signed by the Laboratory Director or the Technical Consultant and the testing personnel. 2. Review of the instrument printouts showed that proficiency testing samples were run more than once for samples that did not meet the patient's samples criteria for re-running the sample. a. The laboratory ran the following hematology samples twice that did not meet the criteria for rerunning the sample: 2024 3rd event samples #11, #12, and #15; and 2025 1st event sample #1, #2, and #4. b. The laboratory ran the following coagulation samples twice that did not meet the criteria for rerunning the sample: 2024 3rd event samples #11, #13, and #15; and 2025 1st event samples #1, #2, #3, and #4. c. The laboratory ran the following chemistry sample twice that did not meet the criteria for rerunning the sample: 2024 3rd event samples #13, #14, and #15; and 2025 2nd event samples #6, #8, and #10. d. The laboratory ran the following hCG samples twice that did not meet the criteria for re-running the sample for 2025 2nd event samples #6, #8, #9 and #10. 3. Review of the laboratory's policy titled, Policy for Proficiency Testing (PT) Handling and Results Submission noted, Testing Personnel run PT samples by "Testing PT samples in the same manner as patients, except where the nature of the PT material requires special handling." 4. During an interview on 07/17/2025 at 1:05 PM, Testing Personnel A acknowledged the samples were run twice.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have Testing Personnel competencies performed for Technical Consultants in the position of Testing Personnel signed by the Laboratory Director for 1 of 1 Techincal Consultants, (A). Findings included: Review of CMS-209 revealed Technical Consultant is also testing personnel A. Review of Testing Personnel competencies revealed the following: 1. Testing Personnel A's 6 month competency was performed on 5/15/2024 and was performed by the former Technical Consultant. 2. Testing Personnel A's annual competency was performed on 2/21 /2025 and was performed by former Technical Consultant. Review of the laboratory's Policy and Process for Performance Assessment of Delegated Duties signed by the Laboratory Director on 6/13/2025 read, "The Laboratory Director evaluates the performance of the Technical Consultant on each the following duties." On 7/17/2025 at 11:18 AM, Technologist B stated the former Technical Consultant stopped working in the laboratory in February 2024 and stated his signature was listed on the competency assessments.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.

	This STANDARD is not met as evidenced by: Based on observation, review of the procedure manual, and interview, the laboratory reported a patient's test results for Prothrombin Time (PT), international Normalization Index and Partial Thromboplastin Time (PTT) past the stability of the sample for one (#1) of 39 (#1 - #39) patient collection tubes examined. Findings: 1. Observations on 07/16/2024 at 1:05 PM, revealed one patient's sample that was collected in an expired Sodium Citrate tube lot #4011406 expired on 10/31/2024 in a rack of run tubes. The laboratory used sodium citrate tube for testing the following analytes: prothrombin time (PT), International Normalized Ratio (INR), and activated partial thromboplastin time. 2. Review of the laboratory's procedure titled, coagulation specimen collection and handling in the listed "Outdated/expired collection tubes" in the section for Rejection Criteria for Unacceptable Specimens. 3. Review of Patient #1's test results report revealed the laboratory reported test results for PT and INR. 4. During an interview on 07/16/25 at 2:15 PM, the Technical Consultant acknowledged the sodium citrate tube was expired.