Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0311066	05/20/2026
Name of Provider or Supplier	**Street Address, City, State**	
Quest Diagnostics Clinical Laboratories, Inc	105 West Stone Drive Suite 1h, Kingsport, TN	

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 onsite validation survey was conducted on May 19, 2026, and completed on May 20, 2026. The laboratory was found to be in compliance with condition level deficiencies. The following standard-level deficiencies were cited.
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: I. Based on a review of the laboratory's policies/procedures, the lack of documented monitoring of received specimen temperatures, and an interview with technical supervisor (TS) #1, the laboratory failed to define the temperature ranges for specimen transportation for 2 of 2 years (May 2024 to May 2026). Findings: 1. Review of a sampling of test system policies on May 19, 2026 revealed the following requirements: a. B-type Natriuretic Peptide (BNP) by Siemens Centaur - "Transport container & temperature: Transport Frozen". b. Troponin HS by Siemens Centaur - "Transport container & temperature: Transport Frozen, NOTE: transport specimen for STAT testing in cold packs or on ice". c. HCG by Siemens Centaur - "Transport container & temperature: transport at room temperature". d. Creatinine, Urine on the Beckman Coulter AU - Series Analyzer: "Transport container & temperature, room temperature". e. Urine Albumin, Urine on the Beckman Coulter AU - Series Analyzer: "Transport container & temperature, room temperature". f. Aspartate Aminotransferase (AST) on the Beckman Coulter AU - Series Analyzer: "Transport container & temperature, room temperature". g. Influenza A and B Antigen Detection,

	Immunoassay, X/pect FLU A & B: "Transport container & temperature: VCM - Preferred refrigerated (cold pack), Acceptable Frozen at less than -20 degrees Celsius (dry ice) and transport swab or saline: acceptable refrigerated (cold pack)". h. Erythrocyte sedimentation rate, Modified Westergren, Excyte Series Automated ESR Analyzer - "Transport container & temperature: same as above, room temperature." i. Wet mount (vaginal) for clue cells, yeast, and trichomonas vaginalis - "Transport container & temperature was not defined in procedure". j. Sysmex XS series Operations for CBC - "Transport container & temperature: see the above, transport at room temperature or refrigerated". k. Sysmex XN series Operations for CBC - "Transport container & temperature: see the above, transport at room temperature." l. PT -INR Prothrombin Time and International Normalized Ratio Sysmex CS-5100/CS-2500/ CA-600 Series Coagulation analyzer: "Transport container & temperature:... sodium citrate - room temperature OR plastic tube for PPP, frozen". m. Partial thromboplastin time, Activated (PTT, APTT, aPTT) CS-5100/CS-2500/ CA-600 Series Coagulation analyzer, Dade Actin FSL -: "Transport container & temperature:... sodium citrate - room temperature OR plastic tube for PPP, frozen". n. Fibrin D-Dimer CA & CS line of analyzers - "Transport container & temperature: Whole blood LB tube, room temperature or refrigerated. PPP: Clean plastic capped vial, frozen or dry ice". 2. The laboratory failed to define specific temperature requirements for room temperature, refrigerated, and frozen. 3. The laboratory failed to provide documentation of temperature monitoring during transport and upon specimen receipt for 2 of 2 years (May 2024 to May 2025). 4. The laboratory performs 1,659,567 clinical tests per year. 5. In the interview on May 19, 2026, at 10: 30 am, the TS#1 confirmed that temperature ranges were not defined, temperatures were not monitored during transport, and temperatures were not monitored upon receipt at the laboratory. II. Based on observation of the specimen receiving area, a review of the laboratory's policies/procedures, the lack of documented monitoring of received specimen temperatures, and an interview with technical supervisor (TS) #1, the laboratory failed to monitor and document the temperature for urine specific gravity by refractometer specimens received for 2 of 2 years (May 2024 to May 2026). Findings: 1. Observation of the specimen receiving area in the laboratory on May 19, 2026, at 10:00 am revealed that the laboratory was not monitoring specimen transport or receipt temperature. 2. Review of the Urine specific gravity by refractometer policy on May 19, 2026, under specimen type and handling revealed the following requirements: "Transport/Storage: Room temperature (15-25 degrees celsius (C))". 3. The laboratory was unable to provide temperature records for specimens received within the past 2 years (May 2024 to May 2026). 4. The laboratory performs 1,659,567 clinical tests per year. 5. During the interview on May 19, 2026, at 10:30 am, the TS#1 confirmed the above findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 observation of the phlebotomy rooms, lack of temperature monitoring documentation and interview with the technical (TC) #2, the laboratory failed to monitor and document the temperature of six of six phlebotomy rooms where vacutainer blood collection tubes were stored. Findings: 1. Observation of phlebotomy rooms on May 20, 2026, at 12:30 pm, revealed six phlebotomy rooms stored Vacuette blood collection tubes and Becton Dickinson (BD) vacutainer blood collection tubes in a blood draw tube organizer attached to the wall. 2. Review of a sampling of the vacutainer blood collection tubes revealed the following manufacturer temperature requirements: a. BD vacutainer blood collection tubes - Sodium Citrate - 4 degrees celsius (C) to 25C. b. BD vacutainer blood collection tubes - Ethylenediaminetetraacetic acid (EDTA) - 4C to 25C. c. Vacuette blood collection tubes - CAT Serum Separator Clot Activator - 4C to 25C. d. Vacuette blood collection tubes - Lithium Heparin (LH) - 4C to 25C. 3. The laboratory was unable to provide documentation for monitored temperature in all 6 phlebotomy rooms based on the manufacturer's requirements. 4. In an interview on May 20, 2026, at 12:45 pm, the TC#2 confirmed temperatures were not being monitored.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observations of the phlebotomy rooms, and an interview with technical consultant (TC) #2, the laboratory failed to ensure 5 of 42 expired sodium citrate vacutainer blood collection that were not available for use in phlebotomy room two. Findings: 1. Observation of phlebotomy rooms on May 20, 2026 at 12:55 pm, revealed six phlebotomy rooms stored Vacuette blood collection tubes and Becton Dickinson (BD) Vacutainer blood collection tubes in a blood draw tube organizer attached to the wall. 2. Review of the blue top BD Sodium Citrate tubes in phlebotomy room two revealed 5 of 42 blood collection tubes were expired and available for use: a. Lot Number 5048252 - one tube - expired 11.30.2025 b. Lot Number 5169791 - two tubes - expired 09.30.2025 c. Lot Number 5169791 - two tubes - expired 03.31.2026 3. In an interview on May 20, 2026, at 1:15 pm, the TC#2 confirmed the above tubes had expired and were available for use.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) (e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on a review of laboratory procedures and an interview with technical supervisor (TS) #1, the laboratory director (LD) failed to ensure approved procedure manuals were available for all aspects of the testing process for 4 of 4 months (February 2026 to May 2026). Findings: 1. The current laboratory director, per ASPEN 116 database, was qualified on February 18, 2026. 2. Review of the laboratory's quality assurance

	(QA) binders (7 in total) revealed the current LD failed to sign 64 of 67 QA policies and procedures before the first day of the survey. 3. In an interview on May 19, 2026, at 10:00 am, TS#1 confirmed that all the QA policies and procedures were not signed by the current LD.