Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2226722	06/26/2025
Name of Provider or Supplier	**Street Address, City, State**	
Quest Diagnostics Mary Bird Perkins Cancer Center	1203 S Tyler Street, Suite #110, Covington, LA	

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	A Recertification survey was performed on June 26, 2025 at Quest Diagnostics Mary Bird Perkins Cancer Center, CLIA ID # 19D2226722. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control (QC) records as well as interview with personnel, the laboratory failed to document quality control mean adjustments for Blood Urea Nitrogen (BUN) testing. Findings: 1. Review of the laboratory's quality control records revealed the laboratory established the following means and standard deviations (SD) for QC Serum Chemistry Control Lot 77950 for Blood Urea Nitrogen (BUN): a) June 5, 2024 *Level 1 - Mean 15.76, SD 0.50 *Level 2 - Mean: 30.08, SD: 0.68 *Level 3 - Mean: 79.32, SD 1.78 b) February 3, 2025 *Level 1 - Mean 15.21, SD 0.50 *Level 2 - Mean: 30.11, SD: 0.68 *Level 3 - Mean: 79.53, SD 1.79 2. In interview on June 6, 2025 at 2:45 p.m., Testing Personnel 1 stated new means were established February 3, 2025 because the laboratory used a new lot of calibrator and laboratory policy required the laboratory to establish new means. 3. Review of the current means and standard deviations in use for lot 77950 in the laboratory information system (LIS) revealed the following means and standard deviations for BUN: *Level 1 - Mean 15.4, SD 0.5 *Level 2 - Mean: 29.5, SD: 0.7 4. Further review of the BUN QC records in the LIS for lot 77950 revealed a comment stating an adjustment was made to BUN on February 26, 2025, but the laboratory did not document the reason for the adjustment and failed to provide raw data to support

	the adjustment. 5. In interview on June 26, 2025 at 3:02 p.m., Testing Personnel 1 confirmed the laboratory did not document why and/or how the means were adjusted for BUN between February 3, 2025 and June 26, 2025.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on observation, review of the laboratory's temperature logs, and interview with personnel, the laboratory failed to perform corrective actions when the room temperature was not maintained within acceptable limits per manufacturer's requirements for forty-four (44) of three hundred seventy-four (374) dates reviewed. Findings: 1. Observation by surveyor during the laboratory tour on June 26, 2025 at 9: 24 a.m. revealed the following items stored at room temperature in the laboratory: a) Beckman Coulter ISE Na+/K+ selectivity check - Manufacturer's storage requirements: 2 - 25 degrees Celsius b) Beckman Coulter ISE Low Serum Standard - Manufacturer's storage requirements: 2 - 25 degrees Celsius c) Beckman Coulter ISE High Serum Standard - Manufacturer's storage requirements: 2 - 25 degrees Celsius 2. Review of the laboratory's temperature logs from January 2024 through June 2025 revealed the laboratory documented daily minimum and maximum temperatures and defined the acceptable room temperature limits as 18 - 30 degrees Celsius which exceeded the manufacturer's upper temperature limit. 3. Further review of the laboratory's temperature logs from January 2024 through June 2025 revealed the laboratory documented room temperatures as outside of the manufacturer's acceptable limits and did not perform corrective actions on the following dates: *January 23, 2024: Max Temp documented as 26 degrees Celsius *February 15, 2024: Max Temp documented as 26 degrees Celsius *March 11, 2024: Max Temp documented as 26 degrees Celsius *April 11, 2024: Max Temp documented as 26 degrees Celsius *April 17, 2024: Max Temp documented as 26 degrees Celsius *April 23, 2024: Max Temp documented as 26 degrees Celsius *April 24, 2024: Max Temp documented as 26 degrees Celsius *April 29, 2024: Max Temp documented as 26 degrees Celsius *May 2, 2024: Max Temp documented as 26 degrees Celsius *May 3, 2024: Max Temp documented as 26 degrees Celsius *May 6, 2024: Max Temp documented as 26 degrees Celsius *May 14, 2024: Max Temp documented as 26 degrees Celsius *May 15, 2024: Max Temp documented as 26 degrees Celsius *May 20, 2024: Max Temp documented as 26 degrees Celsius *May 22, 2024: Max Temp documented as 26 degrees Celsius *May 23, 2024: Max Temp documented as 26 degrees Celsius *May 30, 2024: Max Temp documented as 26 degrees Celsius *May 31, 2024: Max Temp documented as 26 degrees Celsius *June 4, 2024: Max Temp documented as 26 degrees Celsius *June 5, 2024: Max Temp documented as 26 degrees Celsius *June 12, 2024: Max Temp documented as 26 degrees Celsius *July 2, 2024: Max Temp documented as 26 degrees Celsius *July 3, 2024: Max Temp documented as 26 degrees Celsius *July 5, 2024: Max Temp documented as 26 degrees Celsius *July 8, 2024: Max Temp documented as 26 degrees Celsius *October 8, 2024: Max Temp documented as 26 degrees Celsius *October 14, 2024: Max Temp documented as 26 degrees Celsius *October 21, 2024: Max Temp documented as 26 degrees Celsius *October 28, 2024: Max Temp documented as 26 degrees Celsius *November 4, 2024: Max Temp documented as 26 degrees Celsius *November 11, 2024: Max Temp documented as 28 degrees Celsius *November 12, 2024: Max Temp documented as

	26 degrees Celsius *November 13, 2024: Max Temp documented as 26 degrees Celsius *November 14, 2024: Max Temp documented as 26 degrees Celsius *November 15, 2024: Max Temp documented as 26 degrees Celsius *November 18, 2024: Max Temp documented as 29 degrees Celsius *November 19, 2024: Max Temp documented as 26 degrees Celsius *November 20, 2024: Max Temp documented as 26 degrees Celsius *November 21, 2024: Max Temp documented as 26 degrees Celsius *November 22, 2024: Max Temp documented as 27 degrees Celsius *November 25, 2024: Max Temp documented as 27 degrees Celsius *November 26, 2024: Max Temp documented as 27 degrees Celsius *January 23, 2025: Max Temp documented as 26 degrees Celsius *January 24, 2025: Max Temp documented as 26 degrees Celsius 4. In interview on June 26, 2025 at 12:56 p.m., Testing Personnel 1 confirmed the laboratory did not perform corrective actions for the unacceptable temperatures on the dates identified above.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to establish complete procedures to identify issues within the analytic system. Findings: 1. Review of the laboratory policy and procedures revealed the laboratory had a quality assessment process in place; however, the following deficient practices were not identified: a) The laboratory failed to document quality control mean adjustments for Blood Urea Nitrogen (BUN) testing. Refer to D5481. b) The laboratory failed to perform corrective actions when the room temperature was not maintained within acceptable limits per manufacturer's requirements for forty-four (44) of three hundred seventy-four (374) dates reviewed. Refer to D5785.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that quality programs were in place to assure quality laboratory testing. Findings: 1. The laboratory failed to document quality control mean adjustments for Blood Urea Nitrogen (BUN) testing. Refer to D5481. 2. The laboratory failed to establish complete procedures to identify issues within the analytic system. Refer to D5791.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) (e)(7) Ensure that all necessary remedial actions are taken and documented whenever

	significant deviations from the laboratorys established performance specifications are identified, and that patient test results are reported only when the system is functioning properly; This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure corrective actions were performed when deviations from the laboratory's specifications occurred. Refer to D5785.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultants failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Refer to D5481.
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratorys established performance specifications; This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Consultants failed to ensure corrective actions were performed when deviations from the laboratory's policies occurred. Refer to D5785.