Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2013239	10/03/2024
Name of Provider or Supplier	**Street Address, City, State**	
Quest Diagnostics Austin Rrl	3708 Jefferson Street Suite B, Austin, TX	

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	The laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended. Standard level deficiencies were cited.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, test directory, interview, observation, requisition slips, test reports, and pre-survey paperwork, the laboratory failed to monitor and document transport and received temperatures for eight out of eight samples observed on 09/17/2024 and 09/18/2024. Findings follow. A. The laboratory's policies and procedures 1. Total Bilirubin (T Bili) & Direct Bilirubin (D Bili Neo) Review of the laboratory's policy and procedure titled Neonatal Direct Bilirubin on the Beckman Coulter AU Series, approved 07/05/2024; Total Bilirubin on the Beckman Coulter AU Series, approved 07/05/2024: Under 3. Specimen Requirements at 3.2 Specimen Type & Handling stated for Stability and Storage Requirements: Analyte Stability & Storage Requirements a. T Bili Room Temperature: Serum: 3 days b. D Bili Neo Room Temperature: Serum: 24 hours 2. Comprehensive Metabolic Panel (CMP) Review of the laboratory's policies and procedures titled Alkaline Phosphatase (ALP) on the Beckman Coulter AU Series, approved 07/03/2024; Alanine Aminotransferase (ALT) on the Beckman Coulter AU Series, approved 07/16/2024; Total Bilirubin (T Bili) on the Beckman Coulter AU

	Series, approved 07/05/2024; Electrolytes (Na, K, Cl) on the Beckman Coulter AU Series, approved 07/03/2024: Under 3. Specimen Requirements at 3.2 Specimen Type & Handling stated for Stability and Storage Requirements: Analyte Stability & Storage Requirements a. ALP Room Temperature: Serum: 3 days b. ALT Room Temperature: Serum: 3 days c. T Bili Room Temperature: Serum: 3 days d. Na Room Temperature: Serum: 3 days e. K Room Temperature: Serum: 3 days f. Cl Room Temperature: Serum: 3 days 3. Estradiol, Leutinizing Hormone (LH), Progesterone Review of the laboratory's policies and procedures titled Estradiol by Siemens Centaur, approved 07/03/2024; LH by Siemens Centaur, approved 07/05/2024; Progesterone by Siemens Centaur, approved 07/05/2024: Under 3. Specimen Requirements at 3.2 Specimen Type & Handling stated for Stability and Storage Requirements: Analyte Stability & Storage Requirements a. Estradiol Room Temperature: 20 hours b. LH Room Temperature: 8 hours c. Progesterone Room Temperature: 8 hours The policies and procedures did not define what room temperature was in Celsius/Fahrenheit. B. Review of the laboratory's policy and procedure titled Logistics On-Route SOP, prepared 01/31/2022, defines Ambient temperature as "the temperature between 18 - 25 degrees Celsius". C. Review of the on-line Quest Test Directory for the following tests for Transport Temperature and Specimen Stability stated: Analyte/Transport Temperature/Specimen Stability 1. Bilirubin, Total and Direct, Neonatal/Room Temperature/Room Temperature: 24 hours 2. CMP/Room Temperature/Room Temperature: 72 hours 3. Estradiol/Room Temperature/Room Temperature: 7 days 4. LH/Room Temperature/Room Temperature: 7 days 5. Progesterone/Room Temperature/Room Temperature: 72 hours The test directory did not define what room temperature was in Celsius /Fahrenheit. The test directory exceeded the Specimen and Handling requirements of the policies and procedures for the Endocrinology testing. D. Interview with testing personnel #1 (as listed on the CMS Form 209) on 09/17/2024 at 1310 hours in the laboratory stated they don't take temperatures of the samples received, that they feel the samples to determine if they are acceptable. E. Surveyor observed couriers dropping off specimens and had no thermometer or ice packs in a thinly insulated bag. The following samples and requisition slips were dropped off: Observation Accession # Test 1. 09/17/2024@1256 DL 687719P T Bili 2. 09/17/2024@1256 DL 687736 P T Bili, D Bili Neo 3. 09/17/2024@1440 DL 687985 P T Bili, D Bili Neo 4. 09/18 /2024@1027 DL 709003 P T Bili, D Bili Neo 5. 09/18/2024@1030 DL 708852 P Estradiol, LH, Progesterone 6. 09/18/2024@1118 DL 709105 P T Bili, D Bili Neo 7. 09/18/2024@1328 DL 709738 P T Bili, D Bili Neo 8. 09/18/2024@1448 DL 709857 P CMP * Exception: #5 was transported in a insulated bag with an ice pack in a lower separated compartment. F. Interview with the Laboratory Director on 09/18/2024 at 1330 hours in the laboratory confirmed the laboratory had no means to monitor transport and received specimen temperatures. G. Review of the test reports for the above samples showed testing was completed and reported. H. Review of the presurvey paperwork titled Annual Test Volume & Proficiency Programs Worksheet showed an estimated annual test volume of 43,193 in chemistry, and 2,634 in endocrinology.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the

performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:
I. Based on review of the laboratory's policies and procedures, stability studies, interview, and pre-survey paperwork, the laboratory failed to challenge the upper limit of their study on a fresh sample performed on the Beckman Coulter AU 480 for 16 of 16 of its chemistries. Findings follow. A. Review of the laboratory's policies and procedures titled Alkaline Phosphatase (ALP) on the Beckman Coulter AU Series, approved 07/03/2024; Alanine Aminotransferase (ALT) on the Beckman Coulter AU Series, approved 07/16/2024; Neonatal Direct Bilirubin (D Bili Neo) on the Beckman Coulter AU Series, approved 07/05/2024; Total Bilirubin (T Bili) on the Beckman Coulter AU Series, approved 07/05/2024; Cholesterol (Chol) on the Beckman Coulter AU Series, approved 07/03/2024; Creatine Kinase (CK) on the Beckman Coulter AU Series, approved 07/03/2024; Creatinine (Crea) on the Beckman Coulter AU Series, approved 07/03/2024; Gamma Glutamyltransferase (GGT) on the Beckman Coulter AU Series, approved 07/05/2024; Electrolytes (Na, K, Cl) on the Beckman Coulter AU Series, approved 07/03/2024; Direct Low Density Lipoprotein (DLDL) on the Beckman Coulter AU Series, approved 07/03/2024; Lipase on the Beckman Coulter AU Series, approved 07/05/2024; Magnesium (Mg) on the Beckman Coulter AU Series, approved 07/05/2024; Triglycerides (Trig) on the Beckman Coulter AU Series, approved 07/05/2024; Uric Acid (UA) on the Beckman Coulter AU Series, approved 07/05/2024: Under 3. Specimen Requirements at 3.2 Specimen Type & Handling stated for Stability and Storage Requirements: Analyte Stability & Storage Requirements 1. ALP Room Temperature: Serum: 3 days 2. ALT Room Temperature: Serum: 3 days 3. D Bili Neo Room Temperature: Serum: 24 hours 4. T Bili Room Temperature: Serum: 3 days 5. Chol Room Temperature: Serum: 7 days 6. CK Room Temperature: Serum: 3 days 7. Crea Room Temperature: Serum: 3 days 8. GGT Room Temperature: Serum: 7 days 9. Na Room Temperature: Serum: 3 days 10. K Room Temperature: Serum: 3 days 11. Cl Room Temperature: Serum: 3 days 12. DLDL Room Temperature: Serum: 3 days 13. Lipase Room Temperature: Serum: 7 days 14. Mg Room Temperature: Serum: 7 days 15. Trig Room Temperature: Serum: 3 days 16. UA Room Temperature: Serum: 3 days The policies and procedures did not define what room temperature was in Celsius/Fahrenheit. B. Review of the stability studies for the chemistries performed on the Beckman Coulter AU 480, 06/13/2023 - 11/30/2023, did not state the temperatures the samples were exposed to in the study, nor did they challenge the upper range of 25 degrees Celsius at a controlled temperature. In addition, the first sample (0) was not tested on a fresh sample, but a sample received by courier, where temperatures were also not monitored. C. Interview with testing personnel #1 (as listed on the CMS Form 209) on 09/17/2024 at 1310 hours in the laboratory stated the samples were tested in the laboratory at room temperature and the first sample (0) was tested after the courier brought it into the laboratory. He confirmed the baseline sample (0) was tested after exposure to transport temperatures versus using a fresh sample, and the age of the sample was not monitored. D. Review of the presurvey paperwork titled Annual Test Volume & Proficiency Programs Worksheet showed an estimated annual test volume of 43,193 in chemistry. II. Based on review of the manufacturer's instructions, the laboratory's policy and procedure, stability study, patient reports, presurvey paperwork, and interview, the laboratory failed to ensure an extended specimen stability study was

	performed for the Complete Blood Count (CBC) on the Sysmex XN-450 for four out of 14 patient samples reviewed. Findings follow. A. Review of the Sysmex XN-450 Basic Operation manual, 06/2017, at 4.3 Preparing Samples, for Handling Whole Blood stated, "The sample should be analyzed within 4 hours after collection. If it is not possible to analyze the sample within 4 hours, store it in a refrigerator at 2 to 8 degrees Celsius until it can be analyzed..." The manufacturer did not define the stability of the CBC beyond 4 hours after collection. B. Review of the Sysmex XN-450 General Information manual, at Chapter 5 Instrument Specifications stated, "Long term stability is determined by comparing the results of the initial analysis (within 2 hours of collection) to results from samples stored at controlled room and refrigerated temperature for 48 hours..." C. Review of the laboratory's policy and procedure titled Sysmex XNL- Series Operation for CBC, reviewed by previous laboratory director 05 /14/2020, under 3.2 Specimen Type & Stability at Stability and Storage Requirements for High Complexity Sites stated, "High Complexity Room Temperature: 48 hours/ High Complexity Refrigerated: 48 hours". D. The laboratory's specimen stability study was requested on September 18, 2024 at 1355 hours but not provided. E. Random review of patient reports to the STAT Tracking Management Report Summary Detail Report revealed 4 out of 14 exceeded the manufacturer's stability of 4 hours as listed by Accession No, date and time of collection, date and time released, and elapsed time: Accession # Test Collection date and time Released date and time Elapsed Time 1. DL504449M CBC 04/23/2024@0932 04/23/2024@1350 4 hours 18 minutes 2. DL504462M CBC 04/23/2024@0943 04/23/2024@1359 4 hours 16 minutes 3. DZ756240K CBC 06/24/2024@0806 06/24/2024@1213 4 hours 7 minutes 4. DZ039599L CBC 07/16/2024@0728 07/16/2024@1956 12 hours, 28 minutes F. Review of the presurvey paperwork titled Annual Test Volume & Proficiency Programs Worksheet showed an estimated annual test volume of 23,362 for Hematology. G. Interview with technical consultant #1 (as listed on the CMS form 209) on September 18, 2024 at 1355 hours confirmed a stability study to establish the extended specimen stability of the CBC was not performed.