Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2223375	03/01/2022
Name of Provider or Supplier	**Street Address, City, State**	
Quest Diagnostics - Oklahoma City Rrl	4200 W Memorial Rd, Ste 110, Oklahoma City, OK	

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 initial survey was performed on 02/28/2022 and 03/01/2022. The findings were reviewed with the laboratory supervisor and laboratory director at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulation: 493.1409; D6033: Technical Consultant
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (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. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor and laboratory director, the laboratory director or designee failed to sign a proficiency testing attestation statement for one of eight events. Findings include: (1) Surveyor #2 reviewed 2021 proficiency testing records and identified the following for one of eight events: (a) Third 2021 Neonatal Bilirubin (NB-C) Event - The attestation statement had not been signed by the laboratory director or designee; (2) Surveyor #2 reviewed the findings with the laboratory director who stated on 02/28/2022 at 10:50 am, the attestation statement had not been signed by the laboratory director or designee as shown above.

D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) 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 for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor and laboratory director, the laboratory failed to evaluate the accuracy of testing when proficiency results had not been graded by the proficiency program for one of eight proficiency testing events reviewed. Findings include: (1) On 03/01/2022, surveyor #2 reviewed 2021 proficiency testing records. The following was identified for one of eight testing events: (a) Third 2021 General Chemistry Event - five of five result had not been graded by the proficiency testing program: (i) Phosphorus - for the results (CHM-11, CHM-12, CHM-13, CHM-14, CHM-15), the following was identified: (aa) Under "Your Grade" it stated, "See Note [11]", which stated, "Document why the specimens were not analyzed (eg, instrument not functioning or reagents not available). Perform and document alternative assessment (ie, split samples) for the period that commercial PT was not tested to the same level and extent that would have been tested.". (2) Surveyor #2 reviewed the records with the laboratory supervisor and laboratory director. The laboratory supervisor stated on 02/28/2022 at 10:50 am, the laboratory had not evaluated and documented the results that were not graded by the proficiency testing program.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory supervisor and laboratory director, the laboratory failed to follow the manufacturer's instructions for implementing coagulation reagents for two of two new reagents. Findings include: PT REAGENT (1) On 02/28/2022 at 10:20 am, the laboratory supervisor stated to surveyor #1 that PT/INR (Protime/International Normalized Ratio) testing was performed on the Sysmex CA-620 analyzer (serial number# 24306); (2) On 03/01/2022 at 10:00 am, the laboratory supervisor stated to surveyor #2 Innovin reagent lot #549772B, was put into use on 06/08/2021; (3) Surveyor #2 reviewed the manufacturer's instructions for establishing reference intervals, which were as follows: (a) Section V titled, "REFERENCE INTERVAL" under the section titled, "Siemens Coagulation Procedures" stated the following: (i) "A Reference Interval is the interval between and including two reference limits. Reference intervals vary from laboratory to laboratory depending on the population, the technique and reagent lot. Reference intervals for each assay should be established by each institution and verified whenever one or more of the assay/analyzer variables

	are changed." (b) "Requirements:" (i) "Donors must be from a healthy population (no known pathological condition; no presurgical or hospitalized patients)"; (ii) "Donors should not take any medications, including aspirin"; (iii) "Donors should span the adult age range"; (iv) "Note: Reference intervals are typically defined with a 2 SD. Values falling outside this range may or may not be normal and should be further evaluated. Statistically a certain percentage of these patients will be normal. However, by defining the reference range in this manner, patients who are abnormal will less likely to go undetected. (4) Surveyor #2 reviewed the implementation records and identified the following: (a) Normal Reference Range (i) This had been established using 26 samples; (ii) There was no evidence of the medication history and health status of the donors (to ensure a representative sampling of the normal population); (iii) There was no evidence the donors span the adult age range. (5) Surveyor #2 reviewed the records with the laboratory supervisor and laboratory director. The laboratory supervisor stated the following on 03/01/2022 at 11:30 am: (a) The laboratory did not have the documentation to prove the 26 donor samples spanned the adult age range; (b) The laboratory did not have documentation of the donor's medication history and health status. PTT REAGENT (1) On 02/28/2022 at 10:20 am, the laboratory supervisor stated to surveyor #1 that PTT(Partial Thromboplastin Time) testing was performed on the Sysmex CA-620 analyzer (serial number# 24306); (2) On 03/01/2022 at 10:00 am, the laboratory supervisor stated to surveyor #2 the Actin reagent lot #562615A, was put into use on 06/08/2021; (3) Surveyor #2 reviewed the manufacturer's instructions for establishing reference intervals, which were as follows: (a) Section V titled, "REFERENCE INTERVAL" under the section titled, "Siemens Coagulation Procedures" stated the following: (i) "A Reference Interval is the interval between and including two reference limits. Reference intervals vary from laboratory to laboratory depending on the population, the technique and reagent lot. Reference intervals for each assay should be established by each institution and verified whenever one or more of the assay/analyzer variables are changed." (b) "Requirements:" (i) "Donors must be from a healthy population (no known pathological condition; no presurgical or hospitalized patients)"; (ii) "Donors should not take any medications, including aspirin"; (iii) "Donors should span the adult age range"; (iv) "Note: Reference intervals are typically defined with a 2 SD. Values falling outside this range may or may not be normal and should be further evaluated. Statistically a certain percentage of these patients will be normal. However, by defining the reference range in this manner, patients who are abnormal will less likely to go undetected. (4) Surveyor #2 reviewed the implementation records and identified the following: (a) Normal Reference Range (i) This had been established using 26 samples; (ii) There was no evidence of the medication history and health status of the donors (to ensure a representative sampling of the normal population); (iii) There was no evidence the donors span the adult age range. (5) Surveyor #2 reviewed the records with the laboratory supervisor and laboratory director. The laboratory supervisor stated the following on 03/01/2022 at 11:30 am: (a) The laboratory did not have the documentation to prove the 26 donor samples spanned the adult age range; (b) The laboratory did not have documentation of the donor's medication history and health status.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)

	(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of records, written procedure, and interview with the laboratory supervisor and laboratory director, the laboratory failed to ensure the reportable ranges were utilized for one of four new test methods. Findings include: (1) On 02/28 /2022 at 09:50 am, the laboratory supervisor stated to surveyor #1 the laboratory began performing AST (Aspartate Aminotransferase), BUN, Sodium, and Total Bilirubin testing using the Beckman Coulter DXC 700 analyzer on 06/01/2021; (2) On 03/01/2022, surveyor #1 reviewed the performance specification records for the new test system and identified the laboratory had demonstrated the following reportable ranges: (a) AST - 0-467.7 U/L (b) BUN - 5.3-135.2 mmol/L (c) Sodium - 5.0-162 mmol/L (d) Total Bilirubin - 0-18.6 mg/dl (3) With the assistance of the laboratory director, surveyor #1 reviewed the reportable ranges in the procedure manual to show the reportable ranges that were being utilized by the laboratory. The laboratory was using the following reportable ranges: (a) AST - 3-500 U/L (b) BUN - 2-100 mmol/L (c) Sodium - 85-165 mmol/L (d) Total Bilirubin - 0.1-20 mg/dl (4) Surveyor #1 reviewed the findings with the laboratory director who stated on 03/01/2022 at 11:45 am, the laboratory was not using the reportable ranges that had been demonstrated by the laboratory as shown above.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory supervisor and laboratory director, the laboratory failed to follow the manufacturer's instructions for performing weekly maintenance procedures for one of four analyzers. Findings include: (1) On 02/28/2022 at 09:50 am, the laboratory supervisor stated to surveyor #1 the laboratory began performing Albumin, Alkaline Phosphatase, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), BUN, Calcium, Chloride, CO2, Creatinine, Direct Bilirubin, Glucose, Neonatal Bilirubin, Potassium, Sodium, Total Bilirubin, Total Protein, Total Cholesterol, HDL (High Density Lipoprotein), Triglyceride, Magnesium, and Phosphorus testing using the Beckman Coulter DXC 700 analyzer on 06/01/2021; (2) Surveyor #1 reviewed the manufacturer's maintenance requirements as stated on the maintenance log. The weekly requirements were as follows: (a) Clean the Sample Probe and Mix Bars (b) Clean Sample Pre-Dilution Bottle (c) Perform a W-2 (d) Perform a Photocal (e) Enhanced Cleaning of Electrode Line (f) Clean the DI Water Tank and DI Sample Probe Filters (g) Perform Selectivity Check for Na/K Electrodes (3) On 03/01/2022, surveyor #1 reviewed maintenance records from June 2021 through February 2022 and identified the following: (a) Clean the Sample Probe and Mix Bars and Clean Sample Pre-Dilution Bottle had not been documented as performed between 10/28 /2021 and 12/30/2021; (b) Clean the Sample Probe and Mix Bars, Clean Sample Pre-Dilution Bottle, Perform a W-2, Perform a Photocal, Enhanced Cleaning of Electrode

	Line, Clean the DI Water Tank and DI Sample Probe Filters, and Perform Selectivity Check for Na/K Electrodes hd not been documented as performed between: (i) 12/02 /2021 and 12/16/2021 (ii) 12/16/2021 and 12/30/2021 (4) Surveyor #1 reviewed the findings with the laboratory director who stated on 03/01/2022 at 11:20 am, the weekly maintenance had not been documented as performed as identified above.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of patient test reports and interview with the laboratory supervisor and laboratory director, the laboratory failed to ensure reference intervals were available to the authorized person who ordered the tests for three of three patient reports. Findings include: (1) On 02/28/2022 at 09:55 am, the laboratory supervisor stated to surveyor #1 the laboratory began performing CBC (Complete Blood Count) testing, which included the automated differential parameters of % Neutrophils, % Lymphocytes, % Monocytes, % Eosinophils, and % Basophils, using the Siemens Sysmex XN-1000 analyzer on 06/01/2021; (2) On 03/01/2022, surveyor #1 reviewed three patient CBC reports with test dates of 12/09/2021, 12/10/2021, and 12/13/2021. The reports did not include the reference intervals (normal ranges) for % Neutrophils, % Lymphocytes, % Monocytes, % Eosinophils, and % Basophils; (3) Surveyor #1 reviewed the reports with the laboratory supervisor and laboratory director. Both stated on 03/01/2022 at 01:44 pm, the reports did not include the reference intervals as stated above.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor and laboratory director, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or

both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the laboratory supervisor and laboratory director, the laboratory failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications for five of eight proficiency testing attestation forms. Findings include: (1) On 02/28/2022, surveyor #2 reviewed 2021 proficiency testing records and identified that five of eight attestation statements had been signed by an individual who did not meet the minimal educational qualifications of a technical consultant or designee. The attestation statement had been signed by the laboratory supervisor (an individual with a minimum of a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution, and at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service). The following attestation statement had been signed by the laboratory coordinator: (a) Third 2021 Coagulation (CGL-C) Event (b) Third 2021 Clinical Microscopy (CM-B) Event (c) Third 2021 Rapid Strep Antigen (D9-B) Event (d) Third 2021 Infectious mononucleosis (IMW-B) Event (e) Third 2021 Hematology Auto Differential (FH9-C) Event (2) The surveyor reviewed the records with the laboratory supervisor and laboratory director. On 02/28/2022 at 10:40 am, the laboratory director stated the attestation statements, as indicated above, had been signed and dated by an individual who did not meet the regulatory qualification requirements of a technical consultant or designee.