Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2170478	02/02/2024
Name of Provider or Supplier	**Street Address, City, State**	
Quest Diagnostics Health Services	1845 Cherry Street 2nd Floor Lab, Montgomery, AL	

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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of the policy and procedure manual, records for the verification of the manufacturer's performance specifications for the Sysmex CA-620 coagulation analyzer, reviews of the Operator's Manuals, Quality Control (QC) package inserts, reagent storage requirements, and interviews with the Technical Consultant and Testing Personnel #2, the laboratory failed to ensure: a) Manufacturer's requirements were followed for the reconstitution and storage of Coagulation Quality Control (QC) and reagent material. (Refer to D5411) b) The correct water was utilized on the Sysmex CA-620 coagulation analyzer, as per the manufacturer's instructions. (Refer to D5411) c) The storage room temperature was monitored and documented to ensure reagent was stored within the environmental parameters required by the manufacturer. (Refer to D5413) d) The range for acceptable room humidity was updated on the environmental records to reflect manufacturer's requirements for the Sysmex CA-620 coagulation analyzer. (Refer to D5413) e) The Prothrombin Time reference intervals were verified as per the Verification Protocol on the Sysmex CA-620. (Refer to D5421).
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 the laboratory tour, reviews of the policy and procedures manual, the Sysmex CA-620 User Manual, and an interview with Testing Personnel #2, the laboratory failed to ensure: a) manufacturer's requirements were met for reconstitution and storage of Coagulation Quality Control (QC) and reagent material; and b) The correct water was utilized on the Sysmex CA-620 coagulation analyzer. This was noted for nine of nine months. The findings include: 1. During the laboratory tour on 2 /1/2024 at 9:35 AM, the surveyor noted the following: a) Testing personnel reconstituted Citrol Coagulation controls with Deionized water. b) Innovin reagent was stored uncapped on the Sysmex CA-620 coagulation analyzer labeled with a 12-day on-board stability date; and c) Testing personnel utilized purified water in the Rinse bottle water on the Sysmex CA-620 analyzer. 2. A review of the Citrol QC policy on page 9, #6. Quality Control revealed, "...add exactly 1.0 mL [milliliter] of distilled water to each vial." 3. A review of the Innovin policy on page 7, #4.2 Reagent Preparation and Storage revealed, "Reconstituted vials are stable when stored capped: 10 days refrigerated at 2-8 degrees Celsius....On board stability: 24 hours." 4. A review of the CA-620 user manual revealed, "Refill the rinse bottle with distilled water only." 5. During an interview on 2/1/24 at 11:15 AM, Testing Personnel #2 confirmed the laboratory had failed to follow the specified manufacturer's instructions.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 reviews of the environmental records, reagent storage requirements, the Sysmex CA-620 Operator's Manual and an interview with the Technical Consultant, the Laboratory failed to ensure: a) The room temperature (where Hematology Cellpack reagent was stored) was monitored and documented since the previous survey on 7/15/2022. b) The range for acceptable humidity was updated to reflect the manufacturer's environmental requirements for the Sysmex CA-620 coagulation analyzer; this was noted from the date of implementation on 5/5/23 to the date of the survey, 2/1/2024. The findings include: 1. A review of the temperature records revealed no documentation for the storage room in which the cellpack reagent for the Hematology analyzer was stored. The cellpack box specified the following storage temperature requirement: "2-35 degrees Celsius". 2. A review of the humidity records revealed the acceptable range of 15-80% was not updated when the Sysmex CA-620 coagulation analyzer was implemented on 5/5/23. Per the operator's manual under

	installation environment, "...use it at a relative humidity range of 30-85%." 3. During an interview on 2/1/24 at 1:21 PM, the Technical Consultant confirmed the above findings.
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 reviews of the verification of the manufacturer's performance specifications records for the Sysmex CA-620 coagulation analyzer, the Validation protocol, the normal donor consent form, the patient log and an interview with the Technical Consultant, the laboratory failed to ensure reference intervals on the Sysmex CA-620 were verified, as per the "Validation Protocol" before patient testing began. This affected 19 patients and one of one new instruments in use at this facility. The findings include: 1. A review of the Validation Protocol on page 6 revealed, "Donor criteria: 50% male and 50% female. Must be from a healthy population (no known pathological conditions). Record if donor has taken any medications." 2. A review of the Sysmex CA-620 validation records (for the verification of the manufacturer's performance specifications) revealed normal donor consent forms from samples collected to establish normal reference intervals, as follows: a) 30 patients: 18 female, 9 male, and 3 unidentified; the laboratory failed to follow the "Donor Criteria" ratio specified in the Validation Protocol. b) 30 of 30 patients did not answer the question, "...in the past 14 days, have you taken any vitamins, medications, or supplements?" The laboratory failed to include documentation the patient population utilized to establish the reference interval was "healthy", as per the Validation Protocol. 3. A review of the patient log revealed 19 patient Prothrombin Times (PT's) had been performed since patient testing began on 5/5/23. 4. During an interview on 2/1/24 at 12:02 PM, the Technical Consultant confirmed the above findings.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's 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 a review of the Quality Control (QC) records and an interview with Testing Personnel #2, the Laboratory failed to document corrective actions when Coagulation Citrol QC results were outside the acceptable QC range for the Sysmex Ca-620 coag analyzer. This was noted for two days of 8 months of QC records reviewed. The

	findings include: 1. A review of the QC records revealed no documentation of corrective action for 12/13/23 and 1/9/24 when QC was out of range. 2. During an interview on 2/2/24, at 11:02 AM, Testing Personnel #2 confirmed the above findings.