Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2025731	02/10/2022
Name of Provider or Supplier	**Street Address, City, State**	
Quest Diagnostics -Texas City Rrl	7111 Medical Center Drive #200, Texas City, 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 found out of compliance with the following CONDITION LEVEL DEFICIENCIES: D5400- 42 C.F.R. 493.1250 Condition: Analytic Systems Noted deficiencies and plans of correction were discussed with the laboratory representative (s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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 review of the laboratory's policies, review of laboratory's Innovin coagulation reagent rollover studies for 2020, 2021 and 2022 and staff interview it was determined the laboratory failed to meet analytic systems requirements. Findings included: 1. The laboratory failed to ensure the coagulation reagent rollover studies' donor screening documents were completed as per requirements. Refer to D5545. 2. The laboratory failed to ensure Quality Assessments identified and corrected issues

	with documentation of donor screening for coagulation reagent rollover studies. Refer to D5791.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of the laboratory's coagulation reagent rollover studies for 2020, 2021 and 2022 and staff interview it was determined the laboratory failed to ensure the donors for the normal patient study for new lots of Innovin reagent (used on the Sysmex CA 620 coagulation analyzer) had screening documentation as per laboratory's policy requirements. Note: This is a repeat deficiency from the survey conducted on 01/07/2020. Findings included: 1. Review of the laboratory's policy titled "Coagulation Reagent & Control Roll-Over, Validation Protocol" placed into effect 10/13/2020 revealed: "Validation Protocol - Reference Interval Study 1. Performed by all laboratories (primary and local sites). Primary validation sites must test a minimum of 40 normal individuals. All other laboratories must test a minimum of 20 normal individuals. 2. Donor criteria: ... - Preferably medication free. Record medication history which may be used for excluding aberrant results after review with Medical Director. (Refer to donor consent form and questionnaire in the addenda)." 2. Review of the laboratory's coagulation reagent rollover studies of new lots of Innovin reagent (used on the Sysmex CA 620 coagulation analyzer) from January 2020 to February of 2022 revealed there were 2 new lots' of Innovin rollover studies within the above interval as follows: RF20 for Innovin Lot 549772B signed/approved by laboratory director on 09/29/2020 RF21 for Innovin Lot 549798 signed/approved by laboratory director on 01/28/2022 3. Review of the consent and questionnaire forms used for donor screening for the laboratory's coagulation reagent rollover studies revealed the following donors did not have documentation of their medication history: a. RF20 rollover study had 22 donors. The following 5 of the 22 donors did not have their medication history questionnaires filled out: Donor #1 Donor #5 Donor #6 Donor #9 Donor #10 b. RF21 rollover study had 22 donors. The following 20 of the 22 donors did not have their medication history questionnaires filled out, or the questionnaires were not available for review: Donor # 1 Donor #13 Donor # 2 Donor # 14 Donor # 4 Donor # 15 Donor # 5 Donor # 16 Donor # 6 Donor # 17 Donor # 8 Donor # 18 Donor # 9 Donor # 19 Donor # 10 Donor # 20 Donor # 11 Donor # 21 Donor # 12 Donor # 22 4. In an interview on 02/10 /2022 at 1125 hours in the office the Technical Consultant #1 (as described on Form 209 signed by the laboratory director on 02/09/2022), after review of the data, confirmed the findings.
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. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of laboratory's Innovin coagulation reagent rollover studies for 2020, 2021 and 2022 and staff interview it was determined the laboratory's Quality Assessment failed to identify and correct issues with coagulation reagent rollover studies' donor medication history documentation. Refer to D5545
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of laboratory's Innovin coagulation reagent rollover studies for 2020, 2021 and 2022 and staff interview it was determined the Laboratory Director failed to ensure the laboratory's Quality Assessments identified and corrected failures with donor screening documentation. Refer to D5545.