Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0486182	05/03/2019
Name of Provider or Supplier	**Street Address, City, State**	
Quest Diagnostics Fort Worth Rrl	1250 8th Ave Suite 115, Fort Worth, 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	Noted deficiencies and plans of correction were discussed with the laboratory representatives at the entrance and exit conferences. The facility representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. 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 the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of laboratory policy, Siemens Centaur CP (Serial Number ROB20001072) chemistry analyzer calibration records and confirmed in interview, the laboratory failed to follow its own policy for performing calibration verification every 6 months in 2018 to ensure the accuracy of all analytes tested on the Siemens Centaur CP analyzer. Findings included: 1. Review of the laboratory policy titled "Analytical Measurement Range (AMR) Validation and Calibration Verification" (Effective date 08/22/2016; signed by the laboratory director 08/16/2016) stated the following in the section titled "Calibration Verification": "4. Required frequency of

	Calibration Verification/Recalibration ....Laboratories must calibrate a method when it is first placed in service and at least every six months thereafter." 2. Review of the calibration verification records for the Siemens Centaur CP chemistry analyzer revealed Progesterone, Estradiol and Human chorionic gonadotropin (hCG) were tested on the analyzer. Further review of calibration verification records from 2017 and 2018 revealed the laboratory performed calibration verifications in 11/2017 and 11 /2018. This was an elapsed period of 12 months between calibration verifications. The laboratory was asked to provide documentation of calibration verification. No documentation was provided. 4. According to laboratory records, 1968 tests were performed annually. 5. The above findings were confirmed by the Technical Supervisor on 05/03/2019 at 0930 hours in the laboratory office.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: I. Based on direct observation, review of laboratory policy, review of manufacturer's instructions and staff interview, it was revealed the laboratory failed to ensure that 6 of 6 vials of e-Check XS quality control (QC) material were labeled with new expiration dates according to the manufacturer. Findings included: 1. Observed in the laboratory refrigerator on 05/03/2019 at 0945 hours were the following 6 vials e-Check XS QC material in-use for the Sysmex XS 1000iC (Serial Number A1142) hematology analyzer: Lot number 90430804; Expiration date 2019-05-05 Lot number 90930804; Expiration date 2019-06-30 Lot number 90430805; Expiration date 2019-05-05 Lot number 90930805; Expiration date 2019-06-30 Lot number 90430806; Expiration date 2019-05-05 Lot number 90930806; Expiration date 2019-06-30 The vials were NOT labeled with the new expiration date. 2. Review of the laboratory policy titled "Sysmex XS Series Operation for CBC" (Effective date 06/19/2017; approved by the laboratory director 06/20/2017) stated, "NOTE: Labeling requirements for all reagents, calibrators, and controls include: (1) Open date, (2) Substance name, (3) Lot number, (4) Date of preparation, (5) Expiration date, (6) Initials of tech, (7) Any special storage instructions. Check all for visible signs of degradation." 3. Review of the manufacturer's instructions (09/2016, Rev.5) for e-Check XS QC material stated, "Opened and recapped vials and vials whose caps have been pierced will retain stability for 14 days if stored at 2-8 C." 4. The findings were confirmed by the Technical Supervisor on 05/032019 at 0945 hours during a tour of the laboratory. II. Based on direct observation, review of laboratory policy, and staff interview, it was revealed the laboratory failed to ensure that reagents placed on board the Sysmex CA 600 coagulation analyzer (Serial Number 23337) were labeled according to laboratory policy. Findings included: 1. During a tour of the laboratory on 05/03/2019 at 0945 hours, the following reagents were observed on board the Sysmex CA 600 coagulation analyzer: Position 1; Dade Innovin Recombinant Thromboplastin (used for Prothrombin Time testing) Position BI; Clean I Position BII; Clean II The reagents were aliquoted from the original reagent containers into smaller on-board containers. The on-board containers were NOT labeled with the open date, substance name, lot number, or new on-board expiration date. 2. Observed

	in the laboratory refrigerator on 05/03/2019 at 0945 hours were the following coagulation reagents: Dade Innovin Recombinant Thromboplastin; Lot number 549715 A; Expiration date 2020-08-10 Clean I; Lot number A8124; Expiration date 2019-10-17 3. Review of the laboratory policy titled "PT-INR Prothrombin Time & International Normalized Ratio, Sysmex CA600 Series Coagulation Analyzer" (Effective date 02/03/2019; approved by the laboratory director 01/14/2019) stated the following in the section titled "Reagent Preparation and Storage": " Dade Innovin Recombinant Thromboplastin ... .On board stability : 24 hours .... CA Clean I ... ... On board stability 24 hours .....CA Clean II .....On board stability 24 hours. "NOTE: Labeling requirements for all reagents, calibrators, and controls include: (1) Open date, (2) Substance name, (3) Lot number, (4) Date of preparation, (5) Expiration date, (6) Initials of tech, (7) Any special storage instructions. Check all for visible signs of degradation." The laboratory failed to follow its own policy for labeling on-board containers with the open date, substance name, lot number, and new on-board expiration date. 4. During an interview on 05/03/2019 at 0945 hours in the laboratory, testing person #2 stated that a new aliquots of reagents were poured from the original vials every day and that the on board containers were NOT labeled with the on board stability dates. This confirmed the above findings.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory policy, manufacturer's instructions, patient/QC (quality control) log, and confirmed in interview, the laboratory failed to have documentation of an IQCP (individualized quality control plan) to support manufacturer's one level of quality control (control donor) for the PFA-100 analyzer. The laboratory did not include and document two control materials of different concentrations at least once a day patient specimens were tested on PFA-100. Findings included: 1. Review of the laboratory's policy titled "Platelet Function PFA 100" (Effective 02/01/2015; signed by the laboratory director 01/28/2016) stated, "A Control Donor Group is identified and maintained. These individuals will not have von Willebrand disease, any platelet dysfunction disease, and are free of any medication containing acetyl salicylic acid .....An acceptable donor from the Control Donor Group will be analyzed with each shipment of test cartridges, new lot of test cartridges, and after major repair on the PFA-100." The laboratory did not have IQCP procedures to support manufacturer's instructions of control donor, which is less stringent than CLIA requirements. 2. PFA-100 manufacturer's instructions stated, "Control Donor: As part of the instrument quality control, it is recommended to test a control donor in duplicate with each new shipment of cartridges received or whenever the institution wishes to verify the performance of the system. It is recommended that the laboratory run the quality control procedure in a manner consistent with its established quality control program and in conformance with local, state, and/or

	federal regulations or accreditation requirements." 3. Review of PFA patient/QC logs revealed QC for COL/EPI was performed the following days with a control donor: EPI - 03/28/2019 (cartridge lot #5695399; expiration 05/13/2020) Only one level of QC was included for EPI, not two levels of different concentration. The laboratory could NOT provide documentation for the performance of COL/ADP quality control. The laboratory did not have documentation of an IQCP for testing EPI and ADP on the PFA-100. 4. Review of patient/QC log for PFA test revealed the following days (04/19/2019 through 04/30/201) patients were tested for EPI and ADP and two control materials of different concentrations were NOT tested: 04/19/2019 Patient DL424389K01 04/22/2019 Patient DL456708K02 Patient DL456707K03 Patient DL459252K03 Patient DL459254K02 04/23/2019 Patient DL495398K03 Patient DL498364K01 Patient DL498363K03 Patient DL501400K01 04/24/2019 Patient DL531040K01 Patient DL534191K01 Patient IF846636G-02 04/25/2019 Patient DL569989K02 Patient DL569990K02 Patient DL569993K02 Patient DL569994K02 04/29/2019 Patient DL646102K02 Patient DL646103K02 Patient DL647974K02 04 /30/2019 Patient DL676719K02 Patient DL676718K03 Patient DL680119K05 Patient DL680227K02 Patient DL680120K04 Patient DL680228K01 Patient DL680121K03 Patient DL681748K03 Patient IF847244G-02 The laboratory did not include and document two control materials of different concentrations at least once a day patient specimens were tested on the PFA-100. The laboratory did not implement an IQCP to support manufacturer's instructions of control donor, which is less stringent than CLIA requirements. 5. During an interview on 05/03/2019 at 1030 hours, the Technical Supervisor confirmed the above findings.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory policy, manufacturer's instructions, patient/QC (quality control) logs, and confirmed in interview, the laboratory failed to include and document two control materials of different concentrations at least once a day patient specimens were tested for PFA (platelet function assay) for 7 days of testing from 04 /19/2019 through 04/30/2019. Findings included: 1. Review of the laboratory's policy titled "Platelet Function PFA 100" (Effective 02/01/2015; signed by the laboratory director 01/28/2016) stated, "A Control Donor Group is identified and maintained. These individuals will not have von Willebrand disease, any platelet dysfunction disease, and are free of any medication containing acetyl salicylic acid .....An acceptable donor from the Control Donor Group will be analyzed with each shipment of test cartridges, new lot of test cartridges, and after major repair on the PFA-100 ... ... The previously tested normal patient must return values within the normal range for both COL/EPI (collagen/ epinephrine) and COL/ADP (collagen/ adenosine diphosphate)." 2. Review of PFA patient/QC logs revealed QC for COL/EPI was performed the following day with a control donor: EPI - 03/28/2019 (cartridge lot #5695399; expiration 05/13/2020) Only one level of QC was included for EPI, not two levels of different concentration. The laboratory could not provide documentation for the performance of COL/ADP quality control. 3. Review of patient/QC log for

	PFA test revealed the following days (04/19/2019 through 04/30/201) patients were tested for EPI and ADP and two control materials of different concentrations were NOT tested: 04/19/2019 Patient DL424389K01 04/22/2019 Patient DL456708K02 Patient DL456707K03 Patient DL459252K03 Patient DL459254K02 04/23/2019 Patient DL495398K03 Patient DL498364K01 Patient DL498363K03 Patient DL501400K01 04/24/2019 Patient DL531040K01 Patient DL534191K01 Patient IF846636G-02 04/25/2019 Patient DL569989K02 Patient DL569990K02 Patient DL569993K02 Patient DL569994K02 04/29/2019 Patient DL646102K02 Patient DL646103K02 Patient DL647974K02 04/30/2019 Patient DL676719K02 Patient DL676718K03 Patient DL680119K05 Patient DL680227K02 Patient DL680120K04 Patient DL680228K01 Patient DL680121K03 Patient DL681748K03 Patient IF847244G-02 The laboratory did not include and document two control materials of different concentrations at least once a day patient specimens were tested on the PFA-100. The laboratory did not implement an IQCP to support manufacturer's instructions of control donor, which is less stringent than CLIA requirements. Refer to D5445 4. During an interview on 05/03/2019 at 1030 hours, the Technical Supervisor confirmed the above findings.