

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2025731	(X3) Date Survey Completed 01/07/2020
Name of Provider or Supplier Quest Diagnostics -Texas City Rrl	Street Address, City, State 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	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. 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.
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, a review of the laboratory's test records from 2018 and 2019, and staff interview, it was revealed the laboratory failed to have</p>

a method in place to assess the accuracy and precision of test performance by monitoring quality control values over time for urine specific gravity testing on the ATAGO- PAL-10S refractometer. Findings included: 1. A review of the laboratory's policy titled 'Urine Specific Gravity by Refractometer' states the following: "When patient testing is to be performed, run all 3 controls on the refractometer at the beginning of each testing shift, not to exceed 8 hours in between QC runs." 2. A review of the laboratory's test records from 2018, and 2019 revealed the laboratory failed to have documentation of monitoring quality control values over time to detect shifts and trends. The laboratory has been performing urine specific gravity testing on the ATAGO- PAL-10S refractometer since 6/5/2018. 3. The laboratory was asked to provide documentation of having a mechanism in place to monitor the quality control values over time. No documentation was provided. 4. An interview with testing person #1 (as indicated on the CMS 209 form, signed by the laboratory director on 12/20/19) on 1/7/2020 at 12:25 p.m. in the office revealed the laboratory only assessed quality control values each day and did not monitor or evaluate values over time for shifts or trends. This confirmed the above findings.

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 a review of the laboratory's policies, a review of the laboratory's Coagulation Reagent Rollover studies, and staff interview, it was revealed the laboratory failed to have documentation of ensuring samples used for the normal patient study for new lots of Innovin reagent, tested on the Sysmex CA 1500 coagulation analyzer, followed the requirements listed in its policy. Findings include: 1. A review of the laboratory's policy titled 'Laboratory Coagulation Reagent & Control Rollover, Validation Protocol, Local' revealed the following: "Reference Interval Validation Testing: -Each location in the Business Unit must perform a validation of the Reference Interval. This study is also needed to establish the site specific geometric mean normal PT used for the INR calculation. -The addendum includes a consent form and questionnaire for donor screen prior to blood draw. - Donor criteria include healthy individuals who are preferable not on medication (with the exceptions listed below) nor vigorously exercised with the last 18-24 hours. The donors should encompass the age range and gender that patient testing will include. - Volunteers may take vitamins and are allowed one aspirin a day. Any other medications such as Tylenol, Excedrin, sinus headache medication, Aleve or cholesterol medication should be noted on the donor form. If the PT obtained from the medicated donor are not within the existing reference interval, then the medicated donor can be excluded from the data set. If the PT is within the current range, the donor can be included." 2. A review of the laboratory's Coagulation Reagent Rollover studies for new lots of Innovin reagent, tested on the Sysmex CA 1500 coagulation analyzer, were approved by the laboratory director on the following dates: RF18 - 7/9/2018 RF19 - 10/16/2019 3. A review of the consent form and questionnaire used for donor screening for the laboratory's Coagulation Reagent Rollover studies for 2018 and 2019 revealed no documentation regarding the following requirements, as listed in the 'Laboratory Coagulation Reagent & Control Rollover, Validation Protocol,

Local' policy: - whether or not the donors have vigorously exercised within the last 18-24 hours - whether or not the donors have taken one aspirin a day 4. Further review of the consent form and questionnaire used for donor screening for the laboratory's Coagulation Reagent Rollover studies for 2018 and 2019 revealed the following statement at the bottom of each form: "Do you have family or personal history of bleeding disorders or thrombotic episodes? Yes or No" For the Coagulation Reagent Rollover studies done in 2018 and 2019, the following donors failed to document whether they had family or personal history of bleeding disorders or thrombotic episodes: a) RF18 Donor #1 Donor #2 Donor #3 Donor #4 Donor #7 Donor #10 Donor #12 Donor #14 Donor #19 Donor #22 b) RF19 Donor #5 Donor #7 Donor #12

5. An interview with the QA Manager on 01/7/19 at 10:20 a.m. in the office, after review of the records, confirmed the above findings. Key: PT = Prothrombin Time
INR = International Normalized Ratio