

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0500002	<b>(X3) Date Survey Completed</b> 07/03/2018
<b>Name of Provider or Supplier</b> Quest Diagnostics	<b>Street Address, City, State</b> 607 E Sonterra #306, San Antonio, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES: D2000 - 42 C.F.R. 493.801 Condition: Proficiency Testing; Enrollment and Testing of samples D6000 - 42 C.F.R. 493.1403 Condition: Laboratory Director; moderate complexity Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with 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 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.
<b>D2000</b>	<b>ENROLLMENT AND TESTING OF SAMPLES</b> CFR(s): 493.801  Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.  This CONDITION is not met as evidenced by: Based on review of the laboratory's proficiency testing records, review of laboratory communications, review of the laboratory's records, and staff interview, it was

revealed the laboratory failed to meet the criteria for proficiency testing. The findings were: 1. The laboratory altered its reported results to the proficiency testing agency based on communications it had with another laboratory (refer to D2011).

**D2011**

**TESTING OF PROFICIENCY TESTING SAMPLES**

CFR(s): 493.801(b)(3)

Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample (s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's proficiency testing records, review of laboratory communications, review of the laboratory's records, and staff interview, it was revealed the laboratory altered it reported results to the proficiency testing agency based on communications it had with another laboratory. The findings were: 1. A review of the laboratory's College of American Pathologists' (CAP) proficiency testing records for Y-A 2018 Ligand Special revealed the laboratory performed testing on the proficiency testing samples on May 2, 2018. The testing performed was for the analytes of Estradiol and Progesterone. The laboratory's results were: a) Estradiol Y-01 320 Y-02 185 Y-03 2536 (originally >3000, diluted and repeated) NOTE: on 05/11/2018 the results listed above for estradiol were change to a result of "Code 11 unable to analyze". b) Progesterone Y-01 6.4 Y-02 4.0 Y-03 22.3 The results for Y-A 2018 Ligand Special were due by May 15, 2018. 2. A review of the laboratory's policy titled "Proficiency Test Handling and Result Submission" (approved by the laboratory director on 03/25/2015) revealed: "Quest Diagnostics MUST NOT ENGAGE in either Intra- or Inter-laboratory communication about proficiency testing sample(s) before formal evaluation of results by the proficiency testing provided (including communication with another Quest Diagnostics laboratory). If there are concerns about the assay, reagents or run containing a PT sample, contact the Technical Supervisor." And, "There is to be no discussion of any aspect of an active PT event with others outside of the testing lab. Such communications cannot occur until after the results have been formally evaluated by the PT provider." 3. A review of the laboratory's policy titled "PT Inappropriate Referral" (approved by the laboratory director on 04/14/2015) revealed: "- Laboratory personnel must not engage in any inter- or intra-laboratory communications about proficiency testing sample(s) until formal evaluation by the proficiency testing provider. - Laboratory personnel must not discuss any concerns about the assay, reagents, or run containing a PT sample with another laboratory. They must contact their laboratory director for advice; an NOT discuss the issue with another laboratory. - Questions regarding proficiency testing material, testing, or reporting must be directed to the PT provider." In this case, the PT provider was CAP Proficiency Program. 4. Laboratory personnel received an email from another facility (CLIA number 45D0486182) on May 4, 2018 which stated: "Am in Fort Worth RRL and we are doing this survey test for the first time. I need to know if you have greater than result do you guys dilute to obtain a value? I had >3000 and diluted it to obtain 2931. Which do I report to CAP?" 5. The testing facility personnel responded by text with the message: "Yes you are supposed to dilute estradiol x5 with

the diluent" The other facility replied "Thank you" Testing personnel then responded: "And for progesterone too." This sequence indicates the testing laboratory knew the other facility was referring to estradiol sample Y-03 which the laboratory had tested two days prior to the communications. It was the only sample which required dilution and the laboratory's first text only mentioned estradiol testing in the response. 6. A review of the laboratory's investigation report revealed the laboratory manager at the other facility (45D0486182) contacted the regional quality assurance manager on May 7, 2018 and expressed her concerns about a possible inappropriate proficiency testing communications. 7. On May 8, 2018 the regional quality assurance manager contacted the Corporate Medical Operations and Regulations, as well as the laboratory directors of both facilities. 8. On May 9, 2018 the Manager of Laboratory Regulations and Licensure sent an email to the Regional Quality Assurance manager which stated: "This email is being sent to you as notification of an inappropriate inter-laboratory communication of a Proficiency Test (PT) Sample. Quest Diagnostic is self-reporting that on May x, 2018 communication regarding the testing of a PT sample was made between Quest Diagnostics xxx laboratory and Quest Diagnostics xxx laboratory during the active survey. The PT sample was part of the Y Survey for Estradiol. The laboratory will not be submitting a quantitative results for this test...." The email continued: "I just spoke to a CAP Representative to inquire about how to indicate on the PT form that the result will not be submitted. They stated to select the description that best fits the circumstance, i.e. the sample could not be tested." 9. During a phone call with the Regional Quality Assurance manager on 07/03/2018 at 1010 hours in the office it was revealed that she was "told not to report after reaching out to Corporate". The Regional Quality Assurance manager was then asked who the CAP Representative was. She stated that Corporate had contacted the College of American Pathologist Accreditation Division and the CAP Representative. She was unsure if Corporate had contacted the CAP Proficiency Program. 10. In an interview with the laboratory manager on 07/03/2018 in the office it was revealed that she was notified by telephone by the Regional Quality Assurance manager to replace the laboratory's values for estradiol with the code "11". Code "11" for CAP means the laboratory was unable to analyze the samples. 11. Further review of the laboratory's records for Y-A 2018 Ligand-Special proficiency test records revealed the laboratory manager documented on May 11, 2018 that the results for estradiol were changed to a "code "11" unable to analyze per the CAP Representative at CAP" and these altered results were submitted to the proficiency testing agency the same day. 12. A review of the laboratory's instrument records for the Advia Centaur revealed the laboratory failed to have documentation of the instrument not being operational on or around May 2, 2018 when the proficiency testing samples were tested. 13. A review of the laboratory's test records revealed the laboratory performed estradiol testing on 141 patient samples from April 23, 2018 to May 11, 2018, including 12 patient samples tested on May 2, 2018 when the proficiency samples were tested. The patients tested on May 2, 2018 were: DL639736A DL640187A DL640189A DL640377A DL640378A DL640379A DL642232A DL641622A DL642959A DL644695A DL644697A DL644698A 14. An interview with the laboratory manager on 07/03/2018 at 1255 hours in the office confirmed that the instrument was functioning properly, patient samples were being tested and that the code "11" was reported to the proficiency testing agency due to the communications with the other facility. This confirmed the findings.

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**  
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance

with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of the laboratory's College of American Pathologists' proficiency testing records, review of laboratory records, and staff interview, it was revealed the laboratory director failed to ensure the proficiency samples were tested and reported as required (refer to D6016).

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(i)

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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on review of the laboratory's College of American Pathologists' proficiency testing records, review of laboratory records, and staff interview, it was revealed the laboratory director failed to ensure the laboratory did not alter its reporting of results for proficiency testing samples based on communications with another facility (refer to D2011).