| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 45D0500002 | 04/21/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Quest Diagnostics | 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.

| (X4) ID Prefix Tag | Summary Statement of Deficiencies |
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| **D0000** | An initial survey of the facility was performed April 19-21, 2021. Noted deficiency and plans of correction were discussed with the laboratory representatives at the entrance and exit conferences. 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. |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to |

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| | identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's calibration verification records and staff interview, it was revealed the laboratory failed to have documentation of performing calibration verification at least every six months. The findings were: 1. A review of the laboratory's calibration and quality control records for TSH, Estradiol, Serum hCG, and Progesterone performed by the laboratory using the Siemens ADVIA Centaur revealed each utilized 2 or less calibrators and does not run three controls more than once daily. Thus, they required calibration verification at least every six months. 2. A review of the laboratory's calibration verification records from 2019 and 2020 revealed the laboratory failed to have documentation of performing the required calibration verification every six months: Thyroid Stimulating Hormone (TSH) March 2019 June 2019 (3 months) December 2019 (6 months) July 2020 (7 months) a. No other calibration verification records were available for review as of the date of the survey on April 19-21, 2021 (9 months later). Estradiol March 2019 June 2019 (3 months) December 2019 (6 months) July 2020 (7 months) b. No other calibration verification records were available for review as of the date of the survey on April 19-21, 2021 (9 months later). hCG (Human Chorionic Gonadotropin) March 2019 June 2019 (3 months) December 2019 (6 months) July 2020 (7 months) c. No other calibration verification records were available for review as of the date of the survey on April 19-21, 2021 (9 months later). Progesterone March 2019 June 2019 (3 months) December 2019 (6 months) July 2020 (7 months) d. No other calibration verification records were available for review as of the date of the survey on April 19-21, 2021 (9 months later). 3. An interview with General Supervisor #1 (as listed on Form CMS-209) on April 19, 2021 at 14:00 hours in the lab revealed that the laboratory was hoping to move to the upgraded analyzer prior to the calibration verifications needing to be done. |
| **D6055** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's records, review of personnel records and staff interview, it was revealed the laboratory failed to have documentation of the technical consultant assessing the performance of testing personnel prior to patient testing when a new methodology was introduced. The findings were: 1. A review of the laboratory's records revealed the facility starting performing sed rate testing on the Excyte Mini analyzer in March 2020. 2. A review of personnel records revealed competency assessments for personnel performing testing was not performed until: Testing personnel 1 7/31/2020 Testing personnel 2 7/31/2020 Testing personnel 3 7/31 /2020 Testing personnel 4 8/25/2020 3. The laboratory was asked to provide documentation of assessing testing personnel prior to performing patient testing |

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| | starting in March 2020. No documentation was provided. 4. An interview with the laboratory manager on 04/20/2021 at 1300 hours in room 141 confirmed the findings. |