| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 40D2030981 | 06/01/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Laboratorio Clinico Santa Olaya | Barrio Santa Olaya Carretera 829 Km 6 Hm 2, Bayamon, PR | |

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 |
|---|---|
| **D1001** | CERTIFICATE OF WAIVER TESTS<br>CFR(s): 493.15(e)<br><br>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on Alere Afinion AS100 manufacturer's instructions, lack of preventive maintenance records and interview with the technical consultant on June 1, 2018 at 10: 00 AM, it was determined that the laboratory failed to follow manufacturer's instruction for preventive maintenance when 350 out of 350 patients specimens were tested and reported for glycohemoglobin by the Alere Afinion AS100 system from January 4, 2018 to June 1, 2018. The findings include: 1. The laboratory processed the glycohemoglobin tests by the Alere Afinion AS100 system. 2. The Alere Afinion AS100 manufacturer instructed the laboratory to perform every 30 days the cleaning of cartridge chamber. 3. The laboratory did not perform the cleaning of cartridge chamber of the Alere Afinion AS100 system from January 4, 2018 to June 1, 2018. 4. The technical consultant confirmed on June 1, 2018 at 10:00 AM, that the laboratory did not perform the cleaning of cartridge chamber of the Alere Afinion AS100 system from January 4, 2018 to June 1, 2018. 5. From January 4, 2018 to June 1, 2018, the laboratory tested and reported 350 out of 350 patients specimens for glycohemoglobin by the Alere Afinion AS100 system. |
| **D5020** | ENDOCRINOLOGY<br>CFR(s): 493.1212<br><br>If the laboratory provides services in the subspecialty of Endocrinology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and |

| | |
|---|---|
| | 493.1281 through 493.1299.<br><br>This CONDITION is not met as evidenced by:<br>Based on HcG testing records (years 2016 to 2018) review and technical supervisor interview on June 1, 20168 at 11:00 AM, it was determined that the laboratory failed to meet the analytic requirement for Endocrinology (HcG qualitative tests). The finding includes: 1. The laboratory did not include each day of testing a negative and a positive control material when 7 out of 7 patients specimens were tested and reported for HcG qualitative test from June 15, 2017 to April, 20, 2018. Refer to D 5449. |
| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Based on ECI system validation records (years 2016 to 2018) review and interview with the technical supervisor on June 1, 2018 at 10:15 AM, it was determined that the laboratory failed to perform to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population when it validated the following tests: prostatic specific antigen (PSA), Vitamin D, thyroid stimulating hormone (TSH), thyroxin (T4), triodothyronine (T3) and free thyroxin (FT4) on May 31, 2016. The findings include: 1. The laboratory validated the following tests PSA, Vitamin D, TSH, T4, T3 and FT4 on May 31, 2016 by the ECI system. 2. On June 1, 2018 at 10:15 AM, the ECI system validation records showed that the that the laboratory did not verify that the manufacturer's reference intervals (normal values) of those new tests, are appropriate for the laboratory's patient population. 3. The technical supervisor confirmed on June 1, 2018 at 10:15 AM, that the laboratory did not verify that the manufacturer's reference intervals (normal values) of those tests, are appropriate for the laboratory's patient population. 4. From June 1, 2016 to June 1, 2018, the laboratory processed and reported by the ECI system the following patients specimens: Test Patients specimens a. PSA 590 b.TSH 2657 c. T4 676 d. T3 572 e. FT4 386 d. vitamin D 952 |
| **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 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 ECI system calibration verification records (years 2016 to 2018) review and interview with the technical consultant on June 1, 2018 at 10:45 AM, it was determined that the laboratory failed to perform at least once every 6 months the calibration verification of the vitamin D tests processed by the ECI system from June 1, 2016 to June 1, 2018. The findings include: 1. On June 1, 2018 at 10:45 AM, the ECI system calibration verification records showed that laboratory did not perform at least once every 6 months the calibration verification of the vitamin D tests ECI system from June 1, 2016 to June 1, 2018. The laboratory performed the calibration verification of the vitamin D tests on December 8, 2016, May 17, 2017 and January 23, 2018. 2. The technical supervisor confirmed on June 1, 2018 at 10:45 AM, that laboratory did not perform at least once every 6 months the calibration verification of the vitamin D tests by the ECI system. 3. The laboratory processed and reported 952 out of 952 patients specimens for vitamin D by the ECI system from June 1, 2016 to June 1, 2018. |
| **D5449** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(ii)(g)<br><br>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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on HcG testing records (years 2016 to 2018) review and technical supervisor interview on June 1, 20168 at 11:00 AM, , it was determined that the laboratory failed to include each day of testing a negative and a positive control material when 7 out of 7 patients specimens were tested and reported for HcG qualitative test from June 15, 2017 to April, 20, 2018. The findings include: 1. On June 1, 20168 at 11:00 AM, the HcG testing records showed that the laboratory did not include each day of testing a negative and a positive control material when 7 out of 7 patients specimens were tested and reported for HcG qualitative test from June 15, 2017 to April, 20, 2018: patients specimen # 75015 on June 15, 2017, patient specimen # 75231 on June 21, 2017, patient specimen # 28857 on February 6, 2018, patient specimen # 33357 on February 9, 2018, patient specimen # 52857 on February 20, 2018, patient specimen # 85657 on March 19, 2018 and patient specimen # 119657 on April 20, 2018. 2. The |

| | |
|---|---|
| | technical supervisor confirmed on June 1, 20168 at 11:00 AM, that the HcG testing records did not include the documentatio of the quality control procedures those days. She also stated that the control procedures were performed but not recorded. |
| **D6000** | MODERATE COMPLEXITY LABORATORY DIRECTOR<br>CFR(s): 493.1403<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on ECI system validation records (years 2016 to 2018), ECI system calibration verification records (years 2016 to 2018), HcG testing records (years 2016 to 2018) review and interview with the technical consultant on June 1, 2018 at 11:00 AM, it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the laboratory analytical system for routine chemistry and endocrinology specialties. The finding includes: 1. The laboratory director did not comply with the laboratory analytical system for routine chemistry and endocrinology specialties. Refer to D 6020. |
| **D6020** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>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 program is established and maintained to assure the quality of laboratory services provided.<br><br>This STANDARD is not met as evidenced by:<br>Based on ECI system validation records (years 2016 to 2018), ECI system calibration verification records (years 2016 to 2018), HcG testing records (years 2016 to 2018) review and interview with the technical consultant on June 1, 2018 at 11:00 AM, it was determined that the laboratory director failed to comply with the analytic system requirement for routine chemistry and endocrinology specialties. The finding includes: 1. The laboratory director failed to ensure compliance with the analytic system requirement for routine chemistry and endocrinology specialties. Refer to D 5020 Refer to D 5421. Refer to D 5439. |
| **D6042** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(4)<br><br>(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; |

| | |
|---|---|
| | This STANDARD is not met as evidenced by:<br>Based on ECI system validation records (years 2016 to 2018), ECI system calibration verification records (years 2016 to 2018), HcG testing records (years 2016 to 2018) review and interview with the technical consultant on June 1, 2018 at 11:00 AM, it was determined that the technical consultant failed to comply with the analytic system requirement for routine chemistry and endocrinology specialties. Refer to D 5421. Refer to D 5439. Refer to D 5449. |