| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 40D0707929 | 02/15/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Laboratorio Clinico Luis Munoz Rivera | Calle Munoz Rivera #21, Vega Alta, 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 |
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| **D3000** | FACILITY ADMINISTRATION<br>CFR(s): 493.1100<br><br>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.<br><br>This CONDITION is not met as evidenced by:<br>Based on lack of routine chemistry , hematology records and interview with the laboratory director at 8:45 and 9:25 AM on February 15, 2018, it was determined that the laboratory failed to retain quality control records. Refer to D3031. |
| **D3031** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(3)<br><br>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of records and interview with the laboratory director, it was found that the laboratory did not establish policies in order to be able to retrieve their documentation when the main method fails. The findings includes: a. The laboratory |

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| | processed their routine chemistry tests by the Daytona RX instrument. b. At 8:45 AM on February 15, 2018 the laboratory director was required to show the Daytona Rx (routine chemistry) preventive maintenance and quality control records from years 2016 and 2017. c. The laboratory director stated that they performed routine chemistry tests until June 2017. However, the required documentation was kept by the former laboratory nurse after the hurricane, and the laboratory staff had not found it when they returned to work. d. The laboratory director stated that they did not have an alternative method to retrieve the preventive maintenance nor the quality control records from January 2016 to June 2017. The only quality record found was from September 2016. e. At 9:25 AM on February 15, 2018 the laboratory director was required to show the hematology wright stain reactivity check. from years 2016 and 2017. f. The laboratory director stated that they performed manual slide staining, but she cannot retrieve the records by the same reason . |
| **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 endocrinology quality control records review and interview with the laboratory director on February 15, 2018 at 11:45 AM, it was determined that the laboratory failed to ensure compliance with the analytic system requirements for serum hCG (Human Chrorionic Gonadotropin) tests. Refer to D5449. |
| **D5291** | GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1239(a)<br><br>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.<br><br>This STANDARD is not met as evidenced by:<br>Based on Quality Assessment (QA) procedures manual review and laboratory director interview, it was found that laboratory failed to monitor and evaluate the following QA activities: test requisition. The findings includes: a. Review of the Q.A procedure manual on February 15, 2018 at 1:15 PM, showed that evaluation of the completeness of the test requisition must be done every three months. b. Review of the records showed that the laboratory did not evaluate the test requisitions since year 2017. c. The laboratory director stated that the last evaluations were done in year 2016. |
| **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) |

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| | -- (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 review of routine chemistry calibration verification records (year 2015 to 2017) and interview with the laboratory director, it was found that the laboratory did not perform , at least every 6 months, the calibration verification procedures for the routine chemistry tests processed by the Daytona RX instrument. The findings include: a. The laboratory used the Daytona RX instrument to perform routine chemistry tests. b. Review on February 15, 2018 at 9:00 AM of the calibration verification records (kept since the instrument verification procedures) was reviewed. The records showed that calibration verification procedures were scheduled for March and September of each year). c. The laboratory director stated that they processed routine chemistry tests until June 2017. e. The calibration verification were not carried our during year 2016 or 2017. The calibration verification record included results until September 2015. |
| **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 endocrinology quality control records review (year 2016 to 2018) and interview with the laboratory director, it was found that the laboratory failed to include a negative and positive control material when they performed hCG (Human Chrorionic Gonadotropin) tests. The finding include : a. The endocrinology quality control and patient logbook (January 2016 to February 2018) was reviewed on February 15, 2018 at 11:45 AM. b. Review of the logbook showed quality control and patient test records until the week of November 6, 2017. c. The laboratory director stated that she performed more patient's tests , but she decide to report them directly to the information system and forgot to document the external (positive and negative) |

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| | controls and the procedural control each day of testing. d. The laboratory director stated that the workload showed that the laboratory performed twenty (20) hCG patient samples from November 8, 2017 to 2/14/2018. . |
| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(a)(c)<br><br>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on Quality Assessment (QA) procedures manual review and laboratory director interview, it was found that laboratory failed to monitor and evaluate the following QA activities: comparison of test results. The findings includes: a. The Q.A activities for year 2016 to 2018 were reviewed on February 15, 2018 at 1:15 PM. b. The written schedule showed that comparison of the manual differential cell slide reading versus the automated one must be done in January and July of each year. b. Review of the Q. A. records showed that the laboratory did not evaluate the comparison of hematology differential cells reading since year 2016. c. The written schedule showed that comparison of patient test results versus age, sex, diagnostic and others must be done every year d. Review of the Q.A. records showed that the laboratory did not evaluate the comparison of patient test results versus age, sex, diagnostic and others, since year 2016. c. The laboratory director stated that the last evaluations were done in year 2016. |
| **D5891** | POSTANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1299(a)<br><br>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.<br><br>This STANDARD is not met as evidenced by:<br>Based on Quality Assessment (QA) procedures manual review and laboratory director interview, it was found that laboratory failed to monitor and evaluate the following QA activities: test report evaluation. The findings includes: a. The Q.A activities for year 2016 to 2018 were reviewed on February 15, 2018 at 1:15 PM. b. The written schedule showed that evaluation to final test report must be done in March of each year. b. Review of the Q.A. records showed that the laboratory performed the last final test report evaluation in March 2015 c. The laboratory director stated that the last evaluations were done in year 2015. |
| **D6076** | LABORATORY DIRECTOR<br>CFR(s): 493.1441<br><br>The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. |

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| | This CONDITION is not met as evidenced by:<br>Based on quality control records and Q.A. procedures review and laboratory director interview on February 15, 2018 at 1:35 PM, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory quality control and quality assessment requirements. Refer to D 6093 and D 6094. |
| **D6093** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by:<br>Based on review the endocrinology quality control , endocrinology patient test logbook and routine chemistry calibration verification records, it was determined that the laboratory director (sole practitioner) did not make sure that control procedures were maintained for endocrinology and chemistry test. The finding includes: a. The laboratory director did not include external quality control material for hCG test nor performed calibration verification procedures for routine chemistry tests. Refer to D5439 and D5449. |
| **D6094** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by:<br>Based on Quality Assessment (QA) records review and laboratory director interview on February 15, 2018 at 1:30 PM, it was determined that laboratory director failed to ensure compliance with quality assessment (QA) requirements. The finding includes: a. The laboratory director did not follow the schedule evaluations in the Q.A. program for the general laboratory, analytic and the postanalytic systems. Refer to D5291, D5791 and D5891. |