| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 40D0658214 | 03/14/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Laboratorio Clinico Jelmap | Degetau 33, Juana Diaz, 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 review of records, observation and interview with the laboratory director on March 14, 2019, it was found that Laboratorio Clnico Jelmap processed and reported patient's samples without a valid (terminated) CLIA certificate. The finding include:<br>1. The laboratory processed and reported patient's samples from November 2017 to March 14, 2019, however the certificate expired on November 6, 2017. Refer to D 3009 |
| **D3009** | FACILITIES<br>CFR(s): 493.1101(c)<br><br>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, patient's accession lists, Puerto Rico Proficiency Program |

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| | records, CLIA report 0850D, Puerto Rico state laboratories record review, laboratory workload and interview with the laboratory director on March 14, 2019, it was determined that the laboratory collected, processed and reported laboratory tests without a valid (terminated) CLIA certificate. The findings include: 1. On March 11, 2019 the CLIA report 0850D was reviewed to verify the laboratories expiration dates. When the the state record was compared with the CLIA 0850D, it was noticed that Laboratorio Clnico Jelmap, 40D0658214, was not included in the certificates expiring within 12 months. 2. The Puerto Rico Program test scores records were reviewed finding that the laboratory participated during year 2018. 3. An onsite visit to the laboratory was carried out in March 14, 2019 at 8:15 am. it was observed that the laboratory was opened to the public. 4. During interview with the laboratory director at the facility site he stated the following: a. After hurricane Mara the patient's samples were collected and referred to the reference laboratories. b. The laboratory began again to carry out laboratory tests in November 2017. c. That he did not pay the CLIA Certificate due to economic situation with the laboratory. 5. The accession lists of patient's, to whom laboratory services were offered, showed a total of 6,887 patient's from January 2018 to March 14, 2219. 6. The laboratory work load from November 2017 to March 13, 2019, showed that the laboratory processed and reported 63,868 analytes and tests. 7. The laboratory director was informed to stop patient testing. |
| **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.<br><br>This CONDITION is not met as evidenced by:<br>Based on observations, patient's accession lists, workloads records and interview with the laboratory director on March 14, 2019, it was determined that the laboratory director director did not fulfill his responsibilities with the facility administration. Refer to 6079- The laboratory director did not ensure that the laboratory had a valid CLIA certificate to process patient's samples. |
| **D6079** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(a)(b)<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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation and interview with the laboratory director on March 14, 2019 at |

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| | 8:15 a.m., it was determined that the laboratory director failed to be in compliance with the facility administration. The finding include: 1. The laboratory director did not ensure that the laboratory had a valid CLIA certificate to process patient's samples. 2. The Laboratory Clnico Jelmap collected, processed and reported patient's test samples in a facility without a valid (terminated) CLIA certificate since November 6, 2017. Refer to D 3000. |