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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>40D0667456           | <b>(X3) Date Survey Completed</b><br><br>03/15/2022 |
| <b>Name of Provider or Supplier</b><br><br>Lab Clinico Ensenadeno  | <b>Street Address, City, State</b><br><br>J9 Com El Batey, Bo Ensenada, Ensenada, PR |   |
| 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>   |
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| <b>D3009</b>              | <p><b>FACILITIES</b><br/>CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on facility records review (2021-2022) and laboratory general supervisor interview on March 15, 2022, it was determined that the laboratory failed to be in compliance with the Puerto Rico State laboratory regulation. The findings include: 1. The laboratory records showed on March 15, 2022 at 9:00 AM that the Biomedical Generator Number (DBR-RP-29-91-02-0216-RN-21) was due since February 14, 2021. 2. The laboratory general supervisor confirmed on March 15, 2022 at 9:20 AM, that the Biomedical Generator Number was due since February 14, 2021 and the laboratory renew the new Biomedical Generator Number on February 2021. 3. The state law establishes that the Biomedical Generator Number must be renew 60 days before the expired date.</p> |
| <b>D5449</b>              | <p><b>CONTROL PROCEDURES</b><br/>CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on urinalysis quality control records review (years 2021-2022) and laboratory</p>  |

general supervisor interview on March 15, 2022, it was determined that the laboratory failed to follow requirements for quality control when manual microscopic urinalysis examination was performed. The findings include: 1. The laboratory uses URS-10 strips and Clinitek 500 urinalysis instrument for urinalysis patient samples tests. 2. Urinalysis quality control records were reviewed from January 2021 to March 14, 2022, on March 15, 2022, at 10:00 AM. 3. On March 15, 2022, at 10:05 AM the records showed that the laboratory did not include a microscopic negative control material when performed manual microscopic urinalysis examination since January 2021. 4. The laboratory performed and reported one thousand five hundred ninety-one (1,591) in 2021 urinalysis patient's samples and four hundred thirty-four (434) in 2022 urinalysis patient's samples. 5. The laboratory general supervisor confirmed on March 15, 2022, at 10:30 AM that the laboratory did not include a microscopic negative control material each day of testing when performed manual microscopic urinalysis examination since January 2021.

**D6093**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(5)

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.

This STANDARD is not met as evidenced by:  
Based on urinalysis quality control records review (years 2021-2022) and laboratory general supervisor interview on March 15, 2022 at 10:30 AM, it was found that the laboratory director failed to ensure compliance with the urinalysis quality control requirements. Refer to D5449. The findings include: 1. On March 15, 2022 at 10:05 AM, the urinalysis quality control records showed that no negative control material was included. 2. On March 15, 2022 at 10:30 AM the finding was discussed with the laboratory general supervisor. 3. Th laboratory general supervisor stated on March 15, 2022 at 10:40 AM that the laboratory did not include a microscopic negative control material each day of testing when performed manual microscopic urinalysis examinatiion since January 2021.