| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 40D0666940 | 11/16/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Lab Clinico Bacteriologico Lares | Calle San Jose #2, Lares, 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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| **D5405** | PROCEDURE MANUAL<br>CFR(s): 493.1251(c)<br><br>Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.<br><br>This STANDARD is not met as evidenced by:<br>Based on Immuno Card Mycoplasma manufacturer's instructions, Mycoplasma testing records review (year 2020 and 2021) and interview with the laboratory director on November 16, 2021 at 9:25 AM, it was determined that the laboratory failed to follow the manufacturer's instruction when 32 out of 32 patients specimens were tested for Mycoplasma by Immuno Card Meridian method from October 5, 2021 to November 5, 2021. The findings include: 1. The manufacturer's instruction establishes to perform the test procedures at room temperature from 22 to 25 C. 2. On November 16, 2021 at 9:25 AM, the Mycoplasma testing records showed that the laboratory did not monitor nor record the room temperature when patient's specimens were tested for Mycoplasma by Immuno Card Meridian method from October 5, 2021 to November 5, 2021. 3. The laboratory director confirmed on November 16, 2021 at 9:25 AM, that the laboratory did not monitor nor document the room temperature when it processed the patients specimens for Mycoplasma tests. 4. The laboratory processed and reported 32 out of 32 patient specimen for mycoplasma test from October 5, 2021 to November 5, 2021. |
| **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-- |

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| | 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 General Immunology (Mycoplasma pneumoniae test) testing records review (year 2020 and 2021) and interview with the laboratory director on November 16, 2021 at 9:25 AM, it was determined that the laboratory did not include each day of testing an external positive and negative control material when 32 out of 32 patients specimens were tested and reported for of Mycoplasma pneumoniae patient testing from October 5, 2021 to November 5, 2021. The findings include: 1. The laboratory use the Immuno Card Mycoplasma Test Cassette to perform the Mycoplasma pneumoniae qualitative tests. The test was validated on April 24, 2020. 2. On November 16, 2021 at 9:25 AM, review of Mycoplasma pneumoniae testing record showed that the laboratory performs patient testing from October 5, 2021 to November 5, 2021. The laboratory did not include each day of testing the external control materials. 3. The laboratory director confirmed on November 16, 2021 at 9:25 AM, that the laboratory failed to include each day of testing the external negative and positive control material . She stated that the laboratory run the external controls when it received a new reagent kit. 4. The laboratory processed and reported 32 patients specimens for Mycoplasma pneumoniae from October 5, 2021 to November 5, 2021. |
| **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 Immuno Card Mycoplasma manufacturer's instructions, Mycoplasma testing records review and laboratory director interview November 16, 2021 at 9:25 AM, it was determined that the laboratory director failed to ensure that quality control procedures for the Mycoplasma test are maintained in the laboratory. Refer to D 5405 (The laboratory did not monitor nor document the room temperature when patient's specimens were tested for Mycoplasma by Immuno Card Meridian method from October 5, 2021 to November 5, 2021). Refer to D 5449 (The laboratory did not include every day of testing the positive and the negative control materials for the Mycoplasma test). |