| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 40D0907839 | 05/10/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Lab Alejandrino, Inc, Corporation | Carr 177 Km 3, Hm 4, Lomas Verdes Ave, San Juan, 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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| **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 test report records review and laboratory director interview on May 10, 2021 at 8:57 AM, it was determined that the laboratory failed to report the Covid- 19 results as required for 11 out of 12 days reviewed from February 10, 2021 to February 24, 2021. The findings include: 1. The laboratory utilized the Health Department written instruction to reports the Covid-19 results to the Bioportal. 2. The laboratory processed the Covid-19 rapid test by Clarity Block method. 3. The tests report records showed that the laboratory did not report the Covid-19 results in the required frequency (24 hrs) to the Bioportal in 11 out of 12 days reviewed from February 10, 2021 to February 24, 2021: Date Patients Date sent to tested specimens Bioportal 02 /10/2021 2 02/17/2021 02/11/2021 4 02/17/2021 02/12/2021 2 02/17/2021 02/13/2021 6 01/17/2021 02/15/2021 1 02/17/2021 02/17/2021 3 02/26/2021 02/18/2021 2 02/26 /2021 02/19/2021 2 02/26/2021 02/22/2021 5 02/26/2021 02/23/2021 1 02/26/2021 02 /24/2021 1 02/26/2021 4. The laboratory director confirmed on on May 10, 2021 at 8: 57 AM, that those results of Covid-19 IgM and IgG rapid tests were not reported in 24 hrs. |
| **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 |

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| | 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 Mycoplasma IgM testing records (from November 05, 2020 to February 24, 2021), parallel check records review and interview with the laboratory director on May 10, 2021 at 8:57 AM, it was determined that the laboratory failed to include each day of testing a negative and a positives control materials when patients specimens were tested for qualitative Mycoplasma IgM test by the Immuno Card method. The findings include : 1. The parallel check records showed that the laboratory placed in routine use the reagent lot numbers 709030M112 of Mycoplasma IgM by the Immuno Card method on November 05, 2020. 2. The testing records showed that the laboratory did not include each day of testing a negative and a positive control materials when 5 out of 5 patients specimens were tested for qualitative Mycoplasma IgM by the Immuno Card Mycoplasma method from February 17, 2021 to February 24, 2021: Date processed specimen ID 02/17/2021 26810 02/19/2021 26860 02/22 /2021 26902 02/23/2021 26943 02/24/2021 26951 3. The laboratory director confirmed on May 10, 2021 at 8:57 AM, that the laboratory did not include each day of testing a negative and a positive control materials when patients serum specimens were tested for qualitative Mycoplasma IgM tests those days. She stated that the laboratory run a negative and a positive control materials when it places in routine use every new lot of the Immuno Card Mycoplasma reagents Kit. Also the laboratory director stated that the laboratory evaluated and documented the internal control and the room tmperature each day of testing of Mycoplasma IgM tests. |
| **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 Mycoplasma IgM testing records, parallel check records review and interview with the laboratory director on May 10, 2021 at 8:57 AM, it was determined that the laboratory director failed to ensure compliance with the analytic system requirements for the qualitative Mycoplasma IgM test by the Immuno Card method from November 05, 2020 to February 24, 2021. Refer to D 5449 (The laboratory did not include each day of testing a negative and a positives control materials when patients specimens were tested for qualitative Mycoplasma IgM test by the Immuno Card method). |