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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 40D2276609 | (X3) Date Survey Completed 10/10/2024 |
| Name of Provider or Supplier Laboratorio Clinico Irizarry Guash | Street Address, City, State Carretera Pr-121, Km 13 Hm 3 Sec Cuatro Calles, Yauco, 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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| D0000 | The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced CLIA recertification survey at Laboratorio Clinico Irizarry Guasch on October 10, 2024. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following standard level deficiencies were found during the unannounced routine CLIA recertification survey ending on October 10, 2024. |
| D5449 | <p>CONTROL PROCEDURES 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: Based on Mycoplasma pneumoniae IgM test quality control records, patient test worksheet records review and interview with the laboratory testing personnel on October 10, 2024 at 11:20 A.M., it was determined that the laboratory did not include an external positive and negative control material each day of Mycoplasma pneumoniae IgM patient testing. From March 12, 2024 to October 8, 2024, when 122 out of 128 patients were processed and reported. The findings include: 1. The laboratory uses the Immunocard reagent kit to perform Mycoplasma pneumoniae IgM test. 2. Review of Mycoplasma pneumoniae IgM quality control records and patient test worksheet records on October 10, 2024 at 11:00 A.M., showed that the laboratory did not include the external control material each day of patient testing from March 12, 2024 to October 8, 2024. 3. The laboratory testing personnel confirmed on</p> |

October 8, 2024 at 11:20 A.M., that the laboratory failed to include a negative and positive external control material each day of patient testing. From March 12, 2024 to October 8, 2024 the laboratory processed and reported 122 out of 128 patients sample.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

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.

This STANDARD is not met as evidenced by:

Based on Mycoplasma pneumoniae IgM worksheet records review from July 2023 to October 2024, and interview with the laboratory testing personnel on October 10, 2024 at 11:26 AM, it was determined that the laboratory director did not ensure that quality control procedures for the mycoplasma pneumoniae IgM test were being followed. Refer to D5449.