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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 40D0933545 | (X3) Date Survey Completed 08/07/2024 |
| Name of Provider or Supplier Laboratorio Clinico Del Mar | Street Address, City, State Urb San Demetrio, Numero 6, Bloque Q, Vega Baja, 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 DEL MAR on August 7, 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 August 7, 2024. |
| D5471 | <p>CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (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 review (year 2023-2024) , and laboratory director interview on August 7, 2024 at 10:34 A.M., it was determined that the laboratory did not evaluate the new lots of Mycoplasma Pneumoniae IgM test for positive and negative reactivity prior to placing it in routine use. The findings include: 1. On August 7, 2024 at 10:34 A.M., the laboratory director stated that the laboratory performs Mycoplasma Pneumoniae IgM tests with the Immunocard test kit. 2. The Mycoplasma Pneumoniae IgM quality control records were reviewed on August 7, 2024 at 10:38 A.M.from January 1, 2024 to August 7, 2024 and showed that the laboratory did not evaluate the new lots of Mycoplasma Pneumoniae IgM test for positive and negative reactivity prior to placing it in routine use. 3. The laboratory used the following Mycoplasma Pneumoniae IgM lots: a. lot:</p> |

709030Q269, exp. date: 4/12/25, open 2/21/24 b. lot: 709030Q272, exp. date:5/15/25, open 4/18/24 c. lot: 709030Q276, exp. date: 5/15/25, open : 5/9/24 d. lot: 709030Q282, exp. date: 7/9/25, open: 6/25/24 4. The laboratory processed and reported a total of 402 Mycoplasma Pneumoniae IgM patient tests from February 21, 2024 to August 7, 2024. 5. The laboratory director confirmed on August 7, 2024 at 10:41 AM, that the laboratory did not evaluate the new lots of Mycoplasma Pneumoniae IgM tests for positive and negative reactivity prior to placing it in routine use.

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 general immunology quality control records review (2023-2024) , it was determined that the laboratory director did not ensure that the laboratory evaluate the new lots of Mycoplasma Pneumoniae IgM test for positive and negative reactivity prior to placing it in routine use. Refer to D5471.