

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0990488	(X3) Date Survey Completed 06/12/2024
Name of Provider or Supplier Laboratorio Clinico Del Mar Ii	Street Address, City, State Carr 2 Km 42 Bo Algarrobo, 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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on Bacteriology written procedures manual review and technical supervisor interview on June 12, 2024 at 9:41 AM, it was determined that the laboratory failed to follow the established revision schedule for procedure manual. The findings include: 1. On June 12, 2024 at 9:38 AM, the bacteriology procedure manual was reviewed and showed that the laboratory has established that the procedure manual revision must be done every 2 years or with any change of procedure. 2. During the review of the procedure manual on June 12, 2024 at 9:41 AM, it was found that the procedure manual was not reviewed since June 15, 2020. 3. On June 12, 2024 at 9:43 AM, the laboratory technical supervisor confirmed that the laboratory failed to follow the established revision schedule for procedure manual.</p>
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: A. Based on general immunology quality control records and laboratory supervisor</p>

interview on June 12, 2024 at 12:52 PM; it was determined that the laboratory failed to include a negative and positive control material when performed rheumatoid arthritis (RA) qualitative test by Germain method. The laboratory processed and reported five (5) patients samples without quality control material in the following days: February 17, 2024; March 18, 2024, March 26, 2024. The findings include: 1. The laboratory performed RA (rheumatoid factor) by Germain method. 2. On June 12, 2024 at 12:47 PM; the general immunology quality control records were reviewed from January, 2023 to June, 2024. 3. The records showed that the laboratory did not document nor include a negative and positive control material on the following days: February 17, 2024 the laboratory processed and reported one (1) patient; March 18, 2024 the laboratory processed and reported one (1) patient; March 26, 2024 the laboratory processed and reported three (3) patients. 4. The laboratory supervisor and laboratory director confirmed on June 12, 2024 at 12:52 PM; that the laboratory failed to include a negative and positive control material for RA qualitative test in the following days: February 17, 2024; March 18, 2024, March 26, 2024. B. Based on general immunology quality control records and laboratory supervisor interview on June 12, 2024 at 1:20 PM; it was determined that the laboratory failed to include a negative and positive control material when performed C-reactive protein (CRP) qualitative test by Germain method. The laboratory processed and reported five (4) patients samples without quality control material in the following days: January 19, 2024 and March 18, 2024. The findings include: 1. The laboratory performed C-reactive protein (CRP) by Germain method. 2. On June 12, 2024 at 1:12 PM; the general immunology quality control records were reviewed from January, 2023 to June, 2024. 3. The records showed that the laboratory did not document nor include a negative and positive control material on the following days: January 19, 2024 the laboratory processed and reported one (1) patient and on March 18, 2024 the laboratory processed and reported one (3) patient. 4. The laboratory supervisor and laboratory director confirmed on June 12, 2024 at 1:20 PM; that the laboratory failed to include a negative and positive control material for CRP qualitative test in the following days: January 19, 2024 and March 18, 2024

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 test quality control records (year 2023 to 2024) review and interview with the laboratory supervisor on June 12, 2024 at 1:47 PM; it was determined that the laboratory director failed to maintain the quality control procedures for the Rheumatoid arthritis qualitative test. Refer to D5449.

D6106

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(14)

The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.

This STANDARD is not met as evidenced by:

Based on bacteriology procedure manual review and laboratory director interview on June 12, 2024 at 9:41 AM, it was determined that the laboratory director did not evaluate the bacteriology written procedure manual as they have established in the procedure manual, every 2 years or with any change, The last revision was performed on June 15, 2020. Refer to D5407.