

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0705372	(X3) Date Survey Completed 10/12/2022
Name of Provider or Supplier Laboratorio Clinico Del Mar	Street Address, City, State Calle Marginal Pr# 2 Urb Montecarlo #113, 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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on Immuno Card Mycoplasma manufacturer's instructions, Mycoplasma testing records review from February 1, 2022 to October 12, 2022 and laboratory director interview, it was determined that the laboratory failed to follow the manufacturer's instruction when 17 out of 132 patient's specimens were tested over the room temperature (25 C) for Mycoplasma by Immuno Card Meridian method from February 1, 2022 to October 12, 2022. The findings include: 1. Review of the manufacturer's instruction on October 12, 2022 at 10:31 AM, establishes to perform</p>

the test procedures at room temperature from 22C to 25C. 2. On October 12, 2022 at 10:35 AM, the Mycoplasma testing records showed that the laboratory did not take remedial actions when patient's specimens were tested for Mycoplasma by Immuno Card Meridian the room temperature is over the 25 C on April 11, 2022 (one patient), June 9, 2022 (one patient), June 13, 2022 (one patient), June 14, 2022 (one patient), June 22, 2022 (one patient), June 23, 2022 (one patient), July 19, 2022 (one patient), August 23, 2022 (two patient's), September 16, 2022 (three patient's) and September 26, 2022 (five patient's). 3. The laboratory director confirmed on October 12, 2022 at 10:42 AM, that the laboratory did not follow the manufacture's instructions for the temperature of processing these days. 4. The laboratory processed and reported 17 out of 132 patients specimens for Mycoplasma test by Immuno Card Meridian method from February 1, 2022 to October 12, 2022.

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 Immuno Card Mycoplasma manufacturer's instructions, Mycoplasma testing records review from February 1, 2022 to October 12, 2022 and laboratory director interview on October 12, 2022 at 11:54 AM, it was determined that the laboratory director failed to ensure that the laboratory follow the manufacturer's instruction for monitor and documented the room temperature when the patient's specimens were tested for Mycoplasma by Immuno Card Meridian method. Refer to D5403.

D6070

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1425(b)(1)

Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:
Based on Immuno Card Mycoplasma manufacturer's instructions, Mycoplasma testing records review from February 1, 2022 to October 12, 2022 and laboratory director interview on October 12, 2022 at 11:31 AM, it was determined that the testing personnel failed to follow the manufacturer's instruction when patient's were tested for Mycoplasma by Immuno Card Meridian Method. The finding includes: 1. The laboratory testing personnel did not follow the manufacturer's instruction for monitor and documented the room temperature from February 1, 2022 to October 12, 2022 when 17 out of 132 patient's specimens were tested over the room temperature (25 C) for Mycoplasma by Immuno Card Meridian method. Refer to D5403.