

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D1046933	(X3) Date Survey Completed 02/04/2022
Name of Provider or Supplier Lab Clinico Y Bacteriologico Montemar	Street Address, City, State Carr 140 Km 63 Hm 4 Bo Magueyes, Barceloneta, 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
D5405	<p>PROCEDURE MANUAL CFR(s): 493.1251(c)</p> <p>Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.</p> <p>This STANDARD is not met as evidenced by:</p> <ol style="list-style-type: none"> Based on Immuno Card Mycoplasma manufacturer's instructions, General Immunology (Mycoplasma pneumoniae) testing record review (year 2021 and 2022) and interview with the laboratory director on February 4, 2022 at 11:30 AM, it was determined that the laboratory failed to follow the manufacturer's instruction when 779 out of 779 patients specimens were tested and reported for of Mycoplasma pneumoniae from January 04, 2021 to January 25, 2022. The findings include: a. The laboratory use the Immuno Card Mycoplasma Test Cassette to perform the Mycoplasma pneumoniae qualitative tests. b. The manufacturer's instruction establishes to perform the test procedures at room temperature range from 22 to 25 C. c. On February 4, 2022 at 11:30 AM, review of the Mycoplasma pneumoniae testing records showed that the laboratory did not monitor nor document the room temperature when patient's specimens were tested for Mycoplasma by Immuno Card Meridian method from from January 04, 2021 to January 25, 2022. d. The laboratory director confirmed on February 4, 2022 at 11:30 AM, that the laboratory did not monitor nor document the room temperature when it processed the patients specimens for Mycoplasma pneumoniae test. e. The laboratory processed and reported 779 out of 779 patients specimens for Mycoplasma pneumoniae test from January 04, 2021 to January 25, 2022. Based on Dimension system manufacturer's instructions, Cuvette temperature records (years 2021 and 2022) review, laboratory director interview on February 4, 2022 at 12:05 PM, it was determined that the laboratory failed to follow

the manufacturer's instruction for system daily maintenance when 322 out of 3220 patients specimens were processed and reported for comprehensive metabolic panel (CMP) tests by the Dimension Xpand system from January 12, 2021 to December 21, 2021. The findings include: a. The Dimension system manufacturer's requires the Cuvette temperature range from 36.8 C to 37.2 C. b. On February 4, 2022 at 12:05 PM, the Dimension system Cuvette temperature records showed that the laboratory processed and reported 322 patients specimens for CMP tests out of the required manufacturer temperature range during the following days from January 12, 2021 to December 21, 2021: Date cuvette CMP's patients temperature specimens 01/12/2021 36.7 C 60 01/26/2021 36.7 C 56 02/12/2021 36.7 C 49 02/25/2021 36.7 C 59 04/06 /2021 36.7 C 41 09/08/2021 36.4 C 37 12/21/2021 36.7 C 20 c. The laboratory director confirmed on February 4, 2022 at 12:05 PM, that the laboratory processed those patients specimens for CMP tests out of the manufacturer cuvette temperature range from January 12, 2021 to December 21, 2021. e. The laboratory processed 322 patients specimens for CMP tests from January 12, 2021 to December 21, 2021.

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, General Immunology (Mycoplasma pneumoniae) testing record review (year 2021 and 2022), Dimension system manufacturer's instructions, Cuvette temperature records (years 2021 and 2022) review, and laboratory director interview on February 4, 2022 at 12:05 PM, it was determined that the laboratory director did not assure that the established quality control program for Mycoplasma pneumonia tests and for CMP tests were followed. Refer to D 5405 (1) (The laboratory did not monitor nor record the room temperature when patient's specimens were tested for Mycoplasma by Immuno Card Meridian method from January 04, 2021 to January 25, 2022). Refer to D 5405 (2) (The laboratory did not follow the Dimension manufacturer instructions when 22 patients specimens were processed and reported for CMP tests from January 12, 2021 to December 21, 2021).