

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658311	(X3) Date Survey Completed 10/27/2021
Name of Provider or Supplier Quest Diagnostics	Street Address, City, State 214 Las Marias Ave Hyde Park, Rio Piedras, 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: Based on Immuno Card Mycoplasma manufacturer's instructions, Mycoplasma testing records review and laboratory general supervisor interview on October 27, 2021 at 11:54 AM, it was determined that the laboratory failed to follow the manufacturer's instruction when 15 out of 117 patient's specimens were tested for Mycoplasma by Immuno Card Meridian method from July 2, 2021 to October 26, 2021. The findings include: 1. The manufacturer's instruction establishes to perform the test procedures at room temperature from 22C to 25C. 2. On October 27, 2021 at 11:54 AM, the Mycoplasma testing records showed that the laboratory did not monitor nor record the room temperature when patient's specimens were tested for Mycoplasma by Immuno Card Meridian method on August 13, 2021 (five (5) patient's), August 27, 2021 (three (3) patient's), September 9, 2021 (three (3) patient's), October 2, 2021 (two (2) patient's) and October 13, 2021 (two (2) patient's). 3. The laboratory general supervisor confirmed on October 27, 2021 at 11:54 AM, that the laboratory did not monitor nor record the manufacture's instructions for the temperature of processing those days. 4. The laboratory processed and reported 117 patients specimens for mycoplasma test by Immuno Card Meridian method from July 2, 2021 to October 26, 2021.</p>
D6020	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p>

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 and laboratory general supervisor interview on October 27, 2021 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 D5405.

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 and laboratory general supervisor interview on October 27, 2021 at 11: 54 AM, it was determined that the testing personnel failed to follow the manufacturer's instruction when patient's specimens were tested for Mycoplasma by Immuno Card Meridian method from July 2, 2021 to October 26, 2021. Refer to D5405.