

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658206	(X3) Date Survey Completed 09/17/2021
Name of Provider or Supplier Laboratorio Clinico Licer	Street Address, City, State Munoz Rivera No 5, San Lorenzo, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory competence evaluation protocol, personnel records review, lack of technical consultant competency evaluations and laboratory technical consultant interview on September 17, 2021 at 9:00 AM, it was found that the laboratory did not perform the technical consultant competence since January 2020. The findings include: 1. The laboratory competence evaluation protocol showed that personnel competence must be done every year. 2. The personnel records showed that the laboratory director did not evaluate annually the competence of the technical consultant since January 2020. 3. The technical consultant confirmed on September 17, 2021 at 9:00 AM, that her competence evaluations were not performed.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on QA procedures manual review and technical consultant interview on September 17, 2021 at 9:00 AM, it was determined that laboratory failed to monitor</p>

and evaluate the following QA activities: Personnel competency. Refer to D 5209 (The competence of the technical consultant was not evaluated since January 2020).

D5405

PROCEDURE MANUAL

CFR(s): 493.1251(c)

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.

This STANDARD is not met as evidenced by:

Based on Immuno Card Mycoplasma manufacturer's instructions, Mycoplasma testing records and technical consultant interview on September 17, 2021 at 9:45 AM, it was determined that the laboratory failed to follow the manufacturer's instruction when six out of six patient specimen were tested for Mycoplasma by Immuno Card Meridian method from May 29, 2020 to September 16, 2021. The findings include: 1. The manufacturer's instruction establishes to perform the test procedures at room temperature from 22 to 25 C. 2. On September 17, 2021, the Mycoplasma testing records showed that the laboratory did not follow the manufacturer instruction when it processed the following patients specimens: Testing Sample ID Temperature Date processed 1. 05/29/2020 359899 20 C. 2. 09/09/2020 360795 21 C. 3. 09/24/2020 360960 20 C. 4. 10/16/2020 361208 21 C. 5. 12/14/2020 361750 21 C. 6. 09/16/2021 365122 not recorded. 3. The technical consultant confirmed on September 17, 2021 at 9:45 AM, that the laboratory did not follow the manufacture's instructions for the temperature of processing. 4. The laboratory processed and reported six out of six patient specimen for mycoplasma test out of the manufacturer's temperature range from May 29, 2020 to September 16, 2021.

D6042

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(4)

(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

This STANDARD is not met as evidenced by:

Based on Immuno Card Mycoplasma manufacturer's instructions, Mycoplasma testing records and technical consultant interview on September 17, 2021 at 9:45 AM, it was determined that the technical consultant did not ensure that the temperature required by the manufacturer, for the mycoplasma testing process, was maintained during each day of testing. Refer to D 5405 (Temperature out of range on six out of six days).

D6079

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(a)(b)

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, record and report test results promptly, accurately and proficiently,

and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:
Based on Immuno Card Mycoplasma manufacturer's instructions, Mycoplasma testing records and technical consultant interview on September 17, 2021 at 9:45 AM, it was determined that the laboratory director did not fulfill her responsibilities to ensure that the technical consultant are competent to perform the mycoplasma test procedures from May 29, 2020 to September 16, 2021. Refer to D 6042 (The technical consultant did not ensure that the temperature required by the manufacturer, for the mycoplasma testing process, was maintained during each day of testing).

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment 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 QA procedures manual review and technical consultant interview on September 17, 2021 at 9:00 AM, it was determined that laboratory director failed to ensure compliance with QA requirements. 1. Refer to D 5291 (The laboratory director did not follow the schedule evaluations in the QA program for the Personnel competency).