

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0677191	(X3) Date Survey Completed 12/22/2020
Name of Provider or Supplier Laboratorio Clinico Alhambra	Street Address, City, State Calle Comercio #104, Juana Diaz, 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
D2127	<p>HEMATOLOGY CFR(s): 493.851(d)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program records reviewed (2019-2020) and laboratory general supervisor interview on December 22, 2020 at 9:30 A.M., it was determined that the laboratory failed to report the hematology proficiency testing results within the time frame established by the program. The findings include: 1. Proficiency testing records were reviewed from February 2019 to November 2020. 2. The deadline of the second testing event report of hematology tests was August 2, 2019. 3. The laboratory did not report the second testing event of hematology within the time frame established by the Proficiency Testing Program and results in a score of 0 for the testing event. 4. The laboratory general supervisor confirmed on December 22, 2020 at 10:00 A.M. that the laboratory did not report the hematology proficiency testing results of the second testing event within the time frame established by the Proficiency Testing Program.</p>
D3000	<p>FACILITY ADMINISTRATION CFR(s): 493.1100</p> <p>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible</p>

case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.

This CONDITION is not met as evidenced by:
Based on observation of Bacteriology area and interview with the laboratory general supervisor on December 22, 2020 at 12: 00 P.M., it was determined that the laboratory failed to minimized the contamination of patient specimens in the bacteriology area. Refer to D 3001.

D3001

FACILITIES
CFR(s): 493.1101(a)(1)

The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process.

This STANDARD is not met as evidenced by:
Based on observation and laboratory general supervisor interview on December 22, 2020 at 12:00 P.M., it was determined that the laboratory failed to ensure minimized the contamination of patient specimens in the bacteriology area. The findings include:
1. The laboratory had in the area a Vitek 2 system, refrigerator for store reagent and Culture media , a computer system and a small refrigerator over a table used to store foods. 2. Another refrigerator was also observed at the area .The refrigerator contained inside (milk, salad dressing, pancake syrup, sandwish and drinks) . Over the refrigerator observed corn flakes boxes (2) and bottle milk (4) 3. The laboratory general supervisor confirmed on December 22, 2020 the testing area were crowded and the foods refrigerator can not located in the bacteriology area and neither area when patient samples were perform.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:
Based on observation of Bacteriology area and interview with the laboratory general supervisor on December 22, 2020 at 12: 00 P.M., it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory standard of facilities requirements. Refer to D 3001.

D6083

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(2)

The laboratory director must ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed.

This STANDARD is not met as evidenced by:

	<p>Based on bacteriology area observation and interview with the laboratory general supervisor on December 22, 2020 at 12:00 P.M. , it was determined that the laboratory director did ensure that the physical plant in bacteriology area (crowded space) were appropriate for specimen testing and handling. Refer to D 3001.</p>
<p>D6089</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i)</p> <p>The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Program testing records review (2019-2020) and laboratory general supervisor interview on December 22, 2020 at 10:00 AM, it was determined that the laboratory director failed to ensure that proficiency testing samples were tested as required under Subpart H requirements. Refer to D2127.</p>
<p>D6144</p>	<p>GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463</p> <p>The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.</p> <p>This STANDARD is not met as evidenced by: Based on observation of Bacteriology area and interview with the laboratory general supervisor on December 22, 2020 at 12: 00 P.M., it was determined that the laboratory general supervisor failed to ensure compliance with the laboratory standard of facilities requirements. Refer to D 3001.</p>