

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0663834	(X3) Date Survey Completed 12/06/2023
Name of Provider or Supplier Centro De Diagnostico Y Tratamiento De	Street Address, City, State Calle 16 V1 Urb Villa Los Santos, Arecibo, 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
D2093	<p>ROUTINE CHEMISTRY CFR(s): 493.841(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 (2022-2023) and laboratory director interview on December 6, 2023 at 9:30 A.M., it was determined that the laboratory failed to report the routine chemistry and urinalysis proficiency testing results within the time frame established by the program. The findings include: 1. Proficiency testing records were reviewed on December 6, 2023 at 9:30 A.M. from February 2022 to November 2023. 2. The deadline of the second testing event report of routine chemistry and urinalisys was May 20, 2022. (review at 9:40 A.M.) 3. The laboratory director confirmed on December 6, 2023 at 9:45 A.M. that the laboratory failed to report the routine chemistry and urinalysis proficiency testing results of the second testing event within the time frame established by the Proficiency Testing Program.</p>
D2104	<p>ENDOCRINOLOGY CFR(s): 493.843(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 (2022-2023)</p>

	<p>and laboratory director interview on December 6, 2023 at 9:30 A.M., it was determined that the laboratory failed to report the endocrinology proficiency testing results within the time frame established by the program. The findings include: 1. Proficiency testing records were reviewed on December 6, 2023 at 9:30 A.M. from February 2022 to November 2023. 2. The deadline of the second testing event report of endocrinology was May 20, 2022. (review at 9:40 A.M.) 3. The laboratory director confirmed on December 6, 2023 at 9:45 A.M.that the laboratory failed to report the endocrinology proficiency testing results of the second testing event within the time frame established by the Proficiency Testing Program.</p>
<p>D5405</p>	<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, General Immunology (Mycoplasma pneumoniae) testing record review since January 2022 and interview with the laboratory director on December 6, 2023 at 12:45 PM, it was determined that the laboratory failed to follow the manufacturer's instruction when 2, 198 out of 2,198 patients specimens were tested and reported for of Mycoplasma pneumoniae since January 2022. The findings include: 1. The laboratory use the Immuno Card Mycoplasma Test to perform the Mycoplasma pneumoniae qualitative tests. 2. The manufacturer's instruction establishes to perform the test procedures at room temperature range from 22 to 25 C. (review on December 6, 2023 at 12:40 PM) 3. On December 6, 2023 at 12:40 PM, 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. 4. The laboratory director confirmed on December 6, 2023 at 12:45 PM, that the laboratory did not monitor nor document the room temperature when it processed the patients specimens for Mycoplasma pneumoniae test. 5. The laboratory processed and reported 2,198 out of 2,198 patient samples for Mycoplasma pneumoniae test since January 2022.</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 (2022-2023) and laboratory director interview on December 6, 2023 at 9:50 A.M., it was determined that the laboratory director failed to ensure that proficiency testing samples were tested as required under Subpart H requirements. Refer to D2093 and D2104.</p>
<p>D6093</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p>

The laboratory director must ensure that the quality control 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 Mycoplasma pneumonia IgM manufacturer's instructions review and interview with the laboratory director on December 6, 2023 at 12:45 P.M, it was determined that the laboratory director failed to follow the manufacturer's instruction when 2, 198 out of 2,198 patients specimens were tested and reported for of Mycoplasma pneumoniae since January 2022. Refer to D5405.

D6177

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1495(b)(3)

Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:
Based on review of Mycoplasma pneumonia manufacturer's instructions and interview with the laboratory director on December 6, 2023 ar 12:45 P.M, it was determined that the testing personnel did not follow manufacturer's instructions for Mycoplasma pneumonia temperatures requirements. Refer to D5405.