

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 40D0929576	<b>(X3) Date Survey Completed</b> 11/01/2022
<b>Name of Provider or Supplier</b> Laboratorio Clinico Espinosa	<b>Street Address, City, State</b> Carretera #2 Km 27 5 Barrio Espinosa, Dorado, PR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5405</b>	<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 from January 2022 to October 31, 2022 and interview with the laboratory supervisor on November 1, 2022 at 11:15 AM, it was determined that the laboratory failed to follow the manufacturer's instruction when 50 out of 50 patients specimens were tested and reported for of Mycoplasma pneumoniae from January 2022 to October 31, 2022. The findings include: 1. The laboratory use the Immuno Card Mycoplasma Test Cassette 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. 3. On November 1, 2022 at 11:15 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 2022 to October 31, 2022. 4. The laboratory supervisor confirmed on November 1, 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. 5. The laboratory processed and reported 50 patient samples for Mycoplasma pneumoniae test from January 2022 to October 31, 2022.</p>
<b>D5439</b>	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p>

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on routine chemistry calibration verification records review ( year 2021-2022 ), patient results work sheets and laboratory general supervisor interview , it was determined that the laboratory failed to follow manufacturer's calibration verification instructions when performed the calibration verification in year 2022. The findings include: 1. The laboratory used the Chem well T system to perform glucose and lipid panel tests. 2. Review of the routine chemistry calibration verification records showed that the procedures performed in February and August 2022 did not include a maximum value near the upper limit. ( review on November 1, 2022 at 10:52 a.m. ) 3. The Chemwell system reportable range were the following: triglycerides : 0-1000mg /dl cholesterol : 0-500 mg/dl glucose : 0-600 mg/dl hdl ( high density lipoprotein : 2-150 mg/dl 4. On February 2022 the laboratory calibration verification results showed the following values: a. Hdl reportable range ( 2-150 mg/dl ) tested values = 30.9 and 63.2 mg/dl High point -131.2 The high point was obtained by multiply the second value of 63.2 by two ( 2 ) b. cholesterol reportable range (0-500 mg/dl ) tested values = 97 and 201 mg/dl High point -402 The high point was obtained by multiply the second value of 201 by two ( 2 ) c. triglycerides reportable range (0-1000 mg/dl ) tested values = 100 and 191 High point -400 The high point was obtained by multiply the second value by two ( 2 ) d. glucose reportable range (0-600 mg/dl ) tested values = 50 and 104 mg/dl High point -208 The high point was obtained by multiply the second value of 104 by two ( 2 ) 5. On August 2022 the laboratory calibration verification results showed the following values: a. cholesterol reportable range (0-500 mg/dl ) tested values = 96 and 200 mg/dl High point -400 The high point was obtained by multiply the second value of 200 by two ( 2 ) c. triglycerides reportable range (0-1000 mg/dl ) tested values = 98 and 202 High point -404 The high point was obtained by multiply the second value of 202 by two ( 2 ) d. glucose reportable range (0-600 mg/dl ) tested values = 50 and 96 mg/dl High point -192 The high point was obtained by multiply the second value of 96 by two ( 2 ) 6. The General supervisor state on November 1, 2022 at 11:05 a.m. that no calibration verification external material was used to obtain the third point. 7. The laboratory patient results work sheet showed that the laboratory performed and reported the following patients results

and the results were over the reportable range determined by the laboratory calibration verification results : 8/11/22 415368 ( cholesterol- 232 mg/dl ) 415488 ( cholesterol - 206 mg/dl, triglycerides - 261 mg/dl ) 8/18/22 415848 ( cholesterol - 248 mg/dl ) 415998 ( cholesterol - 222 mg/dl, triglycerides - 364 mg/dl ) 415928 ( cholesterol - 244 mg/dl ) 8/25/22 416288 ( cholesterol - 220 mg/dl ) 416298 ( cholesterol - 242 mg /dl ) 416328 ( cholesterol - 234 mg/dl ) 9/1/22 416738 ( cholesterol - 272 mg/dl ) 616748 ( triglycerides - 247 mg/dl ) 416818 ( cholesterol - 258 mg/dl ) 10/20/22 419808 ( cholesterol - 232 mg/dl ) 419768 ( cholesterol - 216 mg/dl ) Review on 11/1 /2022 at 10:55 a.m. 7. The laboratory general supervisor stated on November 1, 2022 at 11:15 a.m. that the laboratory used two calibration material ( control ) and the high value was obtained multiply by 2 the mid- point value.

**D6093**

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

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:  
1. Based on Mycoplasma pneumonia rapid test quality control records ( year 2021-2022 ) and interview with the laboratory general supervisor on November 1, 2022 at 11:30 AM, it was determined that the laboratory director failed to assure that the laboratory follow the manufacturer's instruction when 50 patients specimens were tested and reported for Mycoplasma pneumoniae from January 2022 to October 31, 2022. Refer to D5449. 2. Based on routine chemistry calibration verification records reviewed (years 2021-2022) and laboratory general supervisor interview on November 1, 2022 at 11:30 AM, it was determined that the laboratory director did not assure that establish calibration verification procedures were followed. Refer to D5439.

**D6144**

**GENERAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1463

The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

This STANDARD is not met as evidenced by:  
1. Based on routine chemistry calibration records reviewed (years 2021-2022) and laboratory general supervisor interview on November 1, 2022 at 11:30 AM, it was determined that the general supervisor did not assure that quality control procedures related to calibration and calibration verification procedures were followed. Refer to D5439. 2. Based on Mycoplasma pneumonia rapid test quality control records ( year 2021-2022 ) and interview with the laboratory general supervisor on November 1, 2022 at 11:30 AM, it was determined that the laboratory general supervisor failed to follow the manufacturer's instruction when 50 patients specimens were tested and reported for Mycoplasma pneumoniae from January 2022 to October 31, 2022. Refer to D5449.