

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0693515	(X3) Date Survey Completed 03/03/2022
Name of Provider or Supplier Laboratorio Clinico Camuy	Street Address, City, State Calle Infanzon # 4, Camuy, 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
D5014	<p>GENERAL IMMUNOLOGY CFR(s): 493.1208</p> <p>If the laboratory provides services in the subspecialty of General immunology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on Mycoplasma pneumoniae quality control records patient records review (2021-2022) and interview with the laboratory supervisor, it was determined that the laboratory failed to meet the requirements in the subspecialty of General Immunology. The findings include: 1. The Mycoplasma pneumoniae quality control records showed that laboratory did not include an external positive and a negative control material each day of patient testing. Refer to D5449 2. The laboratory general supervisor confirmed on March 3, 2022 at 12:00 P.M, that the laboratory failed to include each day of testing a negative and positive control material when performed Mycoplasma pneumonia test.</p>
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) records review (2020-</p>

2021) and laboratory general supervisor interview , it was determined that the laboratory failed to verify the accuracy of the hematology specialty when the PRPTP did not have hematology samples in the second testing event performed in June 2021. The findings include: 1. Puerto Rico Proficiency testing records were reviewed from February 2020 to December 2021. 2. In the Hematology second testing event , the PRPTP informed the laboratory that they were not able to ship the scheduled hematology samples. The letter included instructions about, how to verify the accuracy of the missed shipment. 3. The laboratory proficiency testing records showed on March 3, 2022 at 9:35 A.M., that the laboratory did not verify the accuracy of the hematology specialty tests in the second testing event of year 2021. 4. The general supervisor stated on March 3, 2022 at 9:40 A.M., that the laboratory did not verify the accuracy of the hematology tests.

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on General Immunology (Mycoplasma pneumoniae test) quality control records review (years 2021-2022) and laboratory general supervisor interview, it was determined that the laboratory did not include an external positive and negative control material each day of Mycoplasma pneumoniae patient testing. The findings include: 1. General Immunology (Mycoplasma pneumoniae test) quality control records were review on March 3, 2022 at 11:50 A.M., from March 30, 2021 to March 3, 2022. 2. Review of Mycoplasma pneumoniae quality control and patient results record showed that the laboratory did not include any control material each day of patient testing since March 30, 2021. 3. The laboratory general supervisor confirmed on March 3, 2022 at 12:00 P.M, that the laboratory failed to include a negative and positive control material each day of testing when performed Mycoplasma pneumonia test. 4. The laboratory did not include any control material, when 281 out 281 patient specimen were processed and since March 30, 2021.

D5471

CONTROL PROCEDURES
CFR(s): 493.1256(e)(1)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on syphilis serology quality control records review (years 2021-2022) and laboratory general supervisor interview, it was determined that the laboratory did not

	<p>evaluate the new lot of Rapid Plasma reagin (RPR) test for positive and negative reactivity prior to placed it in routine use. The findings include: 1. The laboratory syphilis serology quality control records were review on March 3, 2022 at 11:40 A.M. from January 2021 to March 2022. 2. The laboratory received the following reagent kit for RPR Method and no evaluation of their reactivity was performed when began to use on June 1, 2021: Test Lot Expiration Date RPR 0421275 1/31/23 3. The laboratory processed and reported forty six (46) RPR (Rapid plasma reagin) patient's samples from June 1, 2021 to February 23, 2022. 4. The laboratory general supervisor confirmed on March 3, 2022 at 11:50 A.M. that the laboratory did not evaluate the new lot of Rapid Plasma reagin (RPR) test for positive and negative reactivity prior to placed it in routine use.</p>
<p>D6056</p>	<p>CLINICAL CONSULTANT CFR(s): 493.1415</p> <p>The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part.</p> <p>This CONDITION is not met as evidenced by: Based on personnel records review (2021) and laboratory general supervisor interview , it was determined that the laboratory clinical consultant position is not filled since February 16, 2022. The finding includes: 1. The laboratory general supervisor confirmed on March 3, 2022 at 8:55 A.M., that the previous laboratory clinical consultant resigned on February 16, 2022 and that laboratory position was not filled.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: 1. Based on Mycoplasma pneumonia and syphilis serology quality control records (2021-2022) and interview with the laboratory general supervisor, it was determined that the laboratory director failed to ensure compliance with the requirements for analytic systems. Refer to D6093. 2. Based on laboratory general supervisor interview on March 3, 2022 , it was determined that the laboratory director failed to hire a new clinical consultant . Refer to D 6101.</p>
<p>D6093</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <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.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on Mycoplasma pneumonia and syphilis serology quality control records (2021-2022) and interview with the laboratory general supervisor, it was determined that the laboratory director failed to ensure compliance with the requirements for analytic systems. Refer to D5449 and D5471.

D6101

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(11)

The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart.

This STANDARD is not met as evidenced by:
Based on interview with the laboratory general supervisor on March 3, 2022 , it was found that the laboratory director did not hire a clinical consultant since February 16, 2022. The findings include: 1. The laboratory director did not fill the clinical consultant position. 2. The laboratory general supervisor confirmed on March 3, 2022 at 8:55 A.M., that the laboratory did not fill the clinical consultant position since February 16, 2022.