

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658221	(X3) Date Survey Completed 12/12/2023
Name of Provider or Supplier Lab Clinico Y Bacteriologico Santiago	Street Address, City, State 83 Dr Cueto Suite 3, Utuado, 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) records review (2022-2023) and laboratory general supervisor interview on December 12, 2023 at 9:00 A. M. , it was determined that the laboratory director and testing personnel failed to sign the attestation statements. The findings include: 1. Puerto Rico Proficiency testing records were review from February 2022 to November 2023. (review at 9:05 A.M.) 2. The review of records showed that the laboratory director and laboratory general supervisor (testing personnel) did not sign the attestation statements of the Proficiency testing records from February 2022 to November 2023. (review at 9:05 a. m.) 3. The laboratory general supervisor confirmed on December 12, 2023 at 9:10 A. M.that the laboratory director and general supervisor (testing personnel) failed to sign the attestation statements since 2022.</p>
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 (2022-2023)</p>

and laboratory supervisor interview on December 12, 2023 at 9:17 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. Puerto Rico Proficiency testing records were reviewed from February 2022 to November 2023. 2. The deadline of the second testing event report of hematology tests was June 23, 2023. 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 12, 2023 at 9:25 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.

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 Pregnancy Combo test (One step assay) manufacturer's instruction review, hCG (human chorionic hormone) work sheets records and laboratory general supervisor interview on December 12, 2023 at 11:00 A.M .it was determined that the laboratory failed to follow manufacturer's instruction when report hCG results on January 31, 2023, October 27, 2023 and October 30, 2023. The findings include: 1. The Pregnancy Combo test (One step assay) manufacturer's instruction establish that the interpretation of the results must be as follow : positive : If both C line and T line appear, the test indicates that hCG is detected in the specimen. negative: If only the C line appears , the test indicates that the hCG level in the specimen is not detectable and the result is negative. 2. The hCG work sheets showed that the laboratory reported three hCG patients samples as borderline result the following days: January 31, 2023, October 27, 2023 and October 30, 2023. 3. The laboratory general supervisor confirmed on December 12, 2023 at 11:15 A.M. , that the laboratory failed to follow manufacturer's instruction when report hCG results those days.

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 lack of Mycoplasma Pneumoniae IgM test verification of new lot reactivity records , Mycoplasma Pneumoniae IgM quality control test records (year 2022-2023) , and laboratory general supervisor interview on December 12, 2023 at 11:20 A.M, it

was determined that the laboratory did not evaluate the new lots of Mycoplasma Pneumoniae IgM test for positive and negative reactivity prior to placing it in routine use. The findings include: 1. On December 12, 2023 at 11: 20 A. M, the laboratory general supervisor stated that the laboratory performs Mycoplasma Pneumoniae IgM tests with the Immunocard test kit. 2. The Mycoplasma Pneumoniae IgM quality control test records were reviewed from January 2023 to November 30, 2023 and showed that the laboratory did not evaluate the new lots of Mycoplasma Pneumoniae IgM test for positive and negative reactivity prior to placing it in routine use. (Reviewed on December 12, 2023 at 11:25 A.M) 3. The laboratory general supervisor confirmed that the laboratory used the following lots of Mycoplasma pneumoniae and failed to perform the verification of the new lots for positive and negative reactivity prior to placing it in routine use. Lot number date opened patient testing 709030Q220 4/26/23 192 709030Q236 9/18/23 42 709030Q238 9/30/23 144 4. The laboratory general supervisor confirmed on December 12, 2023 at 11:30 A.M. , that the laboratory did not evaluate the new lots of Mycoplasma Pneumoniae IgM tests for positive and negative reactivity prior to placing it in routine use.

D6089

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(i)

The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.

This STANDARD is not met as evidenced by:
Based on Puerto Rico Proficiency Program testing records review (2022-2023) and laboratory general supervisor interview on December 12, 2023 at 9:00A.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 D2009 and D2127.

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:
Based on endocrinology (hCG) , Mycoplasm pneumoniae quality control record review from January 1, 2022 to December 12, 2023, 2019 and laboratory general supervisor interview on December 12, 2023 at 12:15 p.m. it was determined that the laboratory director failed to ensure compliance with the requirement for analytic systems. The findings include: 1. The laboratory failed to follow manufacturer's instruction when report hCG results. Refer to D5405. 2.The laboratory did not evaluate the new lots of Mycoplasma Pneumoniae IgM test for positive and negative reactivity prior to placing it in routine use. Refer to D5471.

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:

Based on general immunology (Mycoplasma pneumoniae) quality control records review ,endocrinology (hCG) manufacturer's instruction review from January 2022 to December 2023 and laboratory general supervisor interview on December 12, 2023 at 12:15 P.M. it was determined that the general supervisor failed to ensure compliance with the requirement for analytic systems. The finding includes: 1. The laboratory failed to follow manufacturer's instruction when report hCG results. Refer to D5405. 2. The laboratory did not evaluate the new lots of Mycoplasma Pneumoniae IgM test for positive and negative reactivity prior to placing it in routine use. Refer to D5471.