

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0667634	(X3) Date Survey Completed 03/31/2023
Name of Provider or Supplier Laboratorio Clinico Teresita	Street Address, City, State Calle Tomas Jordan #5, 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
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 (year 2022-2023) and interview with the laboratory director on March 31, 2023 at 11: 45 A.M., it was determined that the laboratory failed to meet the requirements in the subspecialty of General Immunology. The finding includes: 1. The laboratory failed to follow the manufacturer's instruction when patients specimens were tested and reported for of Mycoplasma pneumoniae. Refer to D5405. 2.The laboratory did not include an external positive and a negative control material each day of patient testing. Refer to D5449.</p>
D5020	<p>ENDOCRINOLOGY CFR(s): 493.1212</p> <p>If the laboratory provides services in the subspecialty of Endocrinology, 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 serum Human Chorionic Gonadotropin (hCG) test quality control records (years 2022-2023) and interview with the laboratory director on March 31, 2023 at 11: 40 A.M., it was determined that the laboratory failed to ensure compliance with the analytic system requirements for serum hCG qualitative tests. The finding includes: 1.</p>

The human chorionic gonadotropin (hCG) test quality control records (years 2022-2023) showed that the laboratory did not include each day of testing a negative and a positive control material when patients specimens were processed and reported for serum hCG qualitative test. Refer to D 5449.

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:

1. Based on Immuno Card Mycoplasma manufacturer's instructions, General Immunology (Mycoplasma pneumoniae) testing record review from January 10, 2022 to March 31, 2023 and interview with the laboratory director on March 31, 2023 at 10:46 AM, it was determined that the laboratory failed to follow the manufacturer's instruction when 21 out of 202 days patients specimens were tested and reported for Mycoplasma pneumoniae test from January 10, 2022 to March 18, 2023. The findings include: a. The laboratory use the Immuno Card Mycoplasma Test to perform the Mycoplasma pneumoniae qualitative tests. b. The manufacturer's instruction showed that the test procedure must be performed at 22 to 25 C. (review on March 31, 2023 at 10:53 A.M.) c. On March 31, 2023 , the Mycoplasma testing records showed that the laboratory did not follow the manufacturer instruction when processed patients specimens at temperature below 22 C from January 10, 2022 to March 18, 2023. d. The laboratory director confirmed on March 31, 2023 at 11:30 AM, that the laboratory failed to follow the manufacturer's instruction when patients specimens were tested and reported for of Mycoplasma pneumoniae from January 10, 2022 to March 18, 2023. e. The laboratory processed and reported 37 patient samples for Mycoplasma pneumoniae test at temperature below 22 C from January 10, 2022 to March 18, 2023. 2. Based on Immuno Card Mycoplasma manufacturer's instructions, General Immunology (Mycoplasma pneumoniae) testing record review from January 10, 2022 to March 31, 2023 and interview with the laboratory director on March 31, 2023 at 11:30 A.M., it was determined that the laboratory failed to monitor and document the laboratory room temperature when 24 out of 24 patients specimens were tested and reported for of Mycoplasma pneumoniae. The findings include: a. The laboratory use the Immuno Card Mycoplasma Test to perform the Mycoplasma pneumoniae qualitative tests. b. The manufacturer's instruction establishes to perform the test procedures at room temperature range from 22 to 25 C. (review on March 31, 2023 at 11:02 A.M.) c. On March 31, 2023 at 11:02 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 the following days: 4/5/2022, 5/3/2022, 5/5/2022, 5/9/2022 and 5/12/2022. d. The laboratory director confirmed on March 31, 2023 at 11:30 AM, that the laboratory did not monitor nor document the laboratory room temperature when it processed the patients specimens for Mycoplasma pneumoniae test. e. The laboratory processed and reported 24 out of 24 patient samples for Mycoplasma pneumoniae test those days.

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:

1. Based on General Immunology (Mycoplasma pneumoniae test) quality control records review (years 2022-2023) and laboratory director interview on March 31, 2023 at 11:04 A.M. , it was determined that the laboratory did not include an external positive and negative control material each day when the laboratory performed and reported Mycoplasma pneumoniae patient's samples in 93 out of 202 days. The findings include: a. Mycoplasma pneumoniae test quality control records were review January 10, 2022, 2022 to March 18, 2023. (reviewed on march 31, 2023 at 11:11 A. M.) b. Review of Mycoplasma pneumoniae quality control and patient results records showed that the laboratory did not include any control material, each day of patient testing , since June 4, 2022. The laboratory only documented the procedural control with each patient run.(reviewed on march 31, 2023 at 11:12 A.M. c. The laboratory director confirmed on March 31, 2023 at 11:35 A.M, that since June 4, 2022 , the laboratory failed to include a negative and positive control material each day of testing when performed Mycoplasma pneumonia test d. The laboratory did not include any external control material, when 374 out 374 patient specimen were processed and reported from June 4, 2022 to March 18, 2023.(reviewed on march 31, 2023 at 11:12 A.M.) 2. Based on endocrinology quality control records review (2022-2023) and interview with the laboratory director on March 31, 2023 at 11:24 A.M. , it was determined that the laboratory failed to include an external negative and positive control material when performed hCG test 24 out of 74 days . The findings include : a. The laboratory performed hCG (human chorionic gonadotropin) by Aim one step method. b. Endocrinology quality control logs were reviewed from January 2022 to March 31, 2023. c. The records showed that the laboratory did not include a negative and a positive external control material from October 24, 2022 to March 21, 2023. The laboratory only documented the procedural control with each patient run d. The laboratory performed and reported 36 patient samples the following days: 10/24/22, 10/26/22, 11/2/22, 11/7/22, 11/7/22, 11/25/22, 12/1/22, 12/2/22, 12/5/22, 12/7/22, 12/8/22, 12/12/,22, 12/14/22, 12/19/22, 12/27/22, 1/10/23,1/17/23,2/7/23,2/8/23,2/15/23,2/22/23,2/23/23,2/27/23,2/28/23,3/21/23. e. The laboratory director confirmed on March 31, 2023 at 11:45 A.M. , that the laboratory failed to include a negative and positive control material each day of testing when performed hCG test those days.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on General Immunology and endocrinology quality control records, manufacturer's instructions review (year 2022-2023) and laboratory director interview on March 31, 2023 at 11:50 A.M., it was determined that the laboratory

	<p>director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory analytical system requirements. The finding includes: 1. The laboratory director did not comply with the requirement for analytical systems requirements. Refer to D 6020.</p>
<p>D6020</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on general immunology , endocrinology quality control records review (2022-2023) and laboratory director interview on March 31, 2023 at 11:45 AM, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. The findings include: 1. The laboratory failed to follow the manufacturer's instruction when patients specimens were tested and reported for of Mycoplasma pneumoniae. Refer to D5405 2.The laboratory did not include an external positive and negative control material each day when reported and performed Mycoplasma pneumoniae test and hCG test. Refer to D5449.</p>
<p>D6045</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7)</p> <p>(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;</p> <p>This STANDARD is not met as evidenced by: Based on review of new laboratory testing personnel records review (2022) and interview with the laboratory director on March 31, 2023 at 10:00 AM, it was determined that the technical consultant (laboratory director) failed to assure that the new testing personnel hired on March 28, 2022 received an adequate training prior to performed and reported patient samples test.</p>
<p>D6072</p>	<p>TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3)</p> <p>Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.</p> <p>This STANDARD is not met as evidenced by: Based on general immunology , endocrinology (hcg test) , quality control records review (2022-2023) and laboratory director interview on March 31, 2023 at 11:45</p>

AM, it was determined that the laboratory testing personnel failed to ensure compliance with the requirements for analytic systems. The findings include: 1. The laboratory failed to follow the manufacturer's instruction when patients specimens were tested and reported for of Mycoplasma pneumoniae. Refer to D5405 2. The laboratory did not include an external positive and negative control material each day when reported and performed Mycoplasma pneumoniae test and hCG test. Refer to D5449.