

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0667129	(X3) Date Survey Completed 02/19/2021
Name of Provider or Supplier Laboratorio Clinico Del Mar	Street Address, City, State Centro Comercial Plaza Puerta Del Sol, Manati, 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 qualitative Mycoplasma IGM quality control record (from December 18, 2020 to February 2021) review, interview with the laboratory supervisor and laboratory director on February 19, 2021 at 10:05 AM, it was determined that the laboratory failed to meet the requirements in the subspecialty of General Immunology. The finding includes: 1. The laboratory did not include an external positive and negative control material each day of patient testing. Refer to D 5449 (1).</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 endocrinology quality control records review (from September 2020 to January 2021), interview with the laboratory director and general supervisor on February 19, 2021 at 10:20 AM, it was determined that the laboratory failed to meet the requirements in the subspecialty of Endocrinology. The finding includes: a. The laboratory did not include an external positive and negative control material each day of patient testing. Refer to D 5449 (2).</p>

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 qualitative Mycoplasma IGM quality control record (from December 18, 2020 to February 2021) review, interview with the laboratory supervisor and laboratory director on February 19, 2021 at 10:05 AM, it was determined that the laboratory failed to include each day of testing a negative and a positive control materials when 5 out of 7 patients specimens were tested and reported for qualitative Mycoplasma IgM tests from January 9, 2021 to February 4, 2021 by the Immuno Card Mycoplasma method. The findings include: a. On February 19, 2021 at 10:05 AM, the Mycoplasma IGM quality control records showed that the laboratory did not include each day of testing the negative nor the positive control materials the following days from January 9, 2021 to February 4, 2021: Date of patient's tested ID number 01/09 /2021 1186 01/18/2021 1293 01/20/2021 1330 01/29/2021 1431 02/04/2021 1504 b. The laboratory director confirmed on February 19, 2021 at 10:05 AM, that the laboratory did not include the negative nor the positive control material those days. c. The general supervisor stated on February 19, 2021 at 10:05 AM, that the two control materials were included those days but the control results were not recorded. d. The laboratory tested and reported 5 out of 7 patient's specimens for qualitative Mycoplasma IgM tests from January 9, 2021 to February 4, 2021 by the Immuno Card Mycoplasma method. 2. Based on endocrinology quality control records review (from September 2020 to January 2021), interview with the laboratory director and general supervisor on February 19, 2021 at 10:20 AM, it was determined that the laboratory failed to include each day of testing the negative nor the positive control material when patients specimens were tested for qualitative hCG (Human Chorionic Gonadotropin) tests for 10 out of 33 days reviewed from September 18, 2020 to January 25, 2021. The findings include: a. On February 19, 2021 at 10:20 AM, the qualitative hCG testing records showed that the laboratory did not include each day of testing the negative nor the positive control material the following days from September 18, 2020 to January 25, 2021: Date of patient's tested ID number 09/18 /2020 65, 66 01/05/2021 1141, 1149 01/11/2021 1205, 1206, 12,07, 1210 01/12/2021 1224 01/14/2021 1255 01/15/2021 1262, 1276 01/20/2021 1328, 1329, 1331, 1334 01 /21/2021 1343 01/22/2021 1353, 1359 01/25/2021 1384 b. The laboratory director confirmed on February 19, 2021 at 10:20 AM, that the laboratory did not include the negative nor the positive control material those days. c. The general supervisor stated on February 19, 2021 at 10:20 AM, that the two control materials were included those days but the control results were not recorded. d. The laboratory tested and reported 20 patient's specimens for qualitative hCG tests from September 18, 2020 to January 25, 2021.

D6072

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1425(b)(3)

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.

This STANDARD is not met as evidenced by:

Based on qualitative Mycoplasma IGM quality control record, endocrinology quality control records review, interview with the laboratory director and general supervisor on February 19, 2021 at 10:20 AM, it was determined that the laboratory testing personnel no follow quality control procedures for the qualitative Mycoplasma and qualitative hCG tests from September 18, 2020 to February 4, 2021 Refer to D 5449 (1). The laboratory did not include an external positive and negative control material each day of patient testing for qualitative Mycoplasma test. Refer to D 5449 (2). The laboratory did not include an external positive and negative control material each day of patient testing for qualitative hCG test..

D6076

LABORATORY DIRECTOR

CFR(s): 493.1441

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.

This CONDITION is not met as evidenced by:

Based on qualitative Mycoplasma IGM quality control record, endocrinology quality control records review, interview with the laboratory director and general supervisor on February 19, 2021 at 10:20 AM, it was determine that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the laboratory analytical system requirements. The finding includes: 1. The laboratory director did not comply with the analytical systems requirements. Refer to D 6093.

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 qualitative Mycoplasma IGM quality control record, endocrinology quality control records review, interview with the laboratory director and general supervisor on February 19, 2021 at 10:20 AM, it was determined that the laboratory director failed to comply with the analytic requirements for the qualitative Mycoplasma and qualitative hCG tests from September 18, 2020 to February 4, 2021 . Refer to D 5014. The laboratory laboratory failed to meet the requirements in the subspecialty of General Immunology. Refer to D 5020. The laboratory failed to to meet the requirements in the subspecialty of Endocrinology.