

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D2053476	(X3) Date Survey Completed 10/07/2021
Name of Provider or Supplier Laboratorio Clinico Yenimaris	Street Address, City, State Marginal Lomas De Carolina , Carr Pr-3 Km11 Hm 0, Carolina, 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
D5405	<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, Mycoplasma testing records and general supervisor interview on October 7, 2021 on 11:05 AM, it was determined that the laboratory failed to follow the manufacturer's instruction when 137 out of 137 patient's specimens were tested for Mycoplasma by Immuno Card Meridian method from August 4, 2021 to October 2, 2021. The findings include: a. The manufacturer's instruction establishes to perform the test procedures at room temperature from 22 to 25 C. b. On October 7, 2021 on 11:05 AM, the Mycoplasma testing records showed that the laboratory did not monitor nor record the room temperature when patient's specimens were tested for Mycoplasma by Immuno Card Meridian method from from August 4, 2021 to October 2, 2021. b. The laboratory supervisor confirmed on On October 7, 2021 on 11:05 AM, that the laboratory failed to include an external negative and positive control material every day of Mycoplasma testing. Instead the laboratory run the external controls when a new reagent kit lot or shipment were received. c. The general supervisor confirmed on October 7, 2021 on 11:05 AM, that the laboratory did not follow the manufacture's instructions for the temperature of processing. d. The laboratory processed and reported 137 out of 137 patients specimens for mycoplasma test by Immuno Card Meridian method August 4, 2021 to October 2, 2021.</p>
D5439	CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(b)

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 reviewed and general supervisor interview on October 7, 2021 at 10:20 AM, it was determined that the laboratory failed to perform at least every 6 months the calibration verification procedures for the routine chemistry tests processed by the Randox system from October 27, 2020 to April 7, 2021. The findings include: 1. The laboratory processed the comprehensive metabolic panel (CMP) and the lipid profile tests by the Randox system. 2. On October 7, 2021 at 10:20 AM, the Randox system calibration verification records showed that the laboratory did not perform at least every 6 months the calibration verification procedures for the routine chemistry tests from April 27, 2020 to April 8, 2021. The laboratory performed the calibration verification procedures for the routine chemistry tests on April 27, 2020 and April 8, 2021. 2. The laboratory general supervisor confirmed on October 7, 2021 at 10:20 AM, that the laboratory only performed the calibration verification procedures for the routine chemistry those dates. 3. The laboratory processed and reported 1,566 out of 1,566 CMP patients specimens and 1,304 out of 1,304 lipid panel patients specimens tests by the by the Randox system from October 27, 2020 to April 7, 2021.

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 COVID-19 IgM/IgG testing records review, manufacturer instructions for

use (IFU) and interview the laboratory general supervisor on October 7, 2021 at 11:30 AM, it was determined that the laboratory did not include each day of testing an external positive and negative control material when 160 out of 160 patient specimens were reported for Covid-19 IgM/IgG from June 30, 2021 to September 8, 2021. The findings include: a. The laboratory use the Healgen Rapid Test Cassette to perform rapid immunology IgM/IgG patient test. b. The quality control section of the IFU stated that: additional controls may be required according to guidelines or local, state and/or federal regulations (such as 42 CFR 493.1256) or accrediting organizations. c. On October 7, 2021 at 11:30 AM, review of COVID-19 IgM/IgG testing records showed that the laboratory did not include every day of testing the positive and the negative external control materials. Instead the laboratory run the external controls when a new reagent kit lot or shipment were received. d. The laboratory general supervisor confirmed on October 7, 2021 at 11:30 AM, that the laboratory did not include every day of COVID-19 IgM/IgG testing the negative and positive external control materials. e. The laboratory tested and reported 160 out of 160 patient specimens for COVID-19 IgM/IgG test from June 30, 2021 to September 8, 2021. 2. Based on Mycoplasma pneumoniae testing records review and general supervisor interview on October 7, 2021 on 11:05 AM, it was determined that the laboratory did not include an external positive and negative control material each day of Mycoplasma pneumoniae patient testing when 137 out of 137 were testing from August 4, 2021 to October 2, 2021. The findings include: a. On October 7, 2021 on 11:05 AM, the Mycoplasma testing records showed that the laboratory did not include every day of testing the external positive and negative control material from August 4, 2021 to October 2, 2021. b. The laboratory supervisor confirmed on On October 7, 2021 on 11:05 AM, that the laboratory failed to include an external negative and positive control material every day of Mycoplasma testing. Instead the laboratory run the external controls when a new reagent kit lot or shipment were received. c. The laboratory tested and reported 137 out of 137 patient specimens for Mycoplasma Immunocard method from August 4, 2021 to October 2, 2021.

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 Immuno Card Mycoplasma manufacturer's instructions, routine chemistry calibration verification, testing record review and general supervisor interview on October 7, 2021 at 10:20 AM, it was determined that the laboratory director failed to ensure that quality control procedures are maintained in the laboratory. Refer to D 5405 (The laboratory did not monitor nor document the room temperature when patient's specimens were tested for Mycoplasma by Immuno Card Meridian method). Refer to D 5439 (The laboratory did not perform at least every 6 months the calibration verification procedures for the routine chemistry tests processed by the Randox system). Refer to D 5449(1)(2) (The laboratory did not include every day of testing the positive and the negative control materials for the Covid rapid tests and for the Mycoplasma test).