

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D2021124	(X3) Date Survey Completed 08/06/2021
Name of Provider or Supplier Laboratorio Clinico El Cruce	Street Address, City, State Road 119 Km 38 Hm 2 Ramal 435, San Sebastian, 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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on Covid 19 Ag testing records and laboratory director interview on August 6, 2021 at 10:35 a.m., it was determined that the laboratory failed to follow manufacturer's instructions for quality control when patient's specimens were testing for Covid 19 Ag from October 2020 to August 6, 2021 by Id Now COVID-19 Ag method. The findings include : 1. The laboratory performed Covid 19Ag tests since October 2020 by Id Now COVID-19Ag method. 2. The Id Now COVID-19Ag instructions for user establishes the following : a. External Positive and Negative Controls: Good practices suggest the use of positive and negative controls to ensure that test reagents are working and that the test is correctly performed. b. Positive and Negative controls should be tested following the Run QC test instructions on the ID NOW Instrument. A positive control swab is included in the kit. Use a sterile swab as the negative control swab. 3. On August 6, 2021 at 10:35 a.m., the Covid 19 Ag testing records showed that the laboratory did not run a negative control with each new lot or box. 4. The laboratory director confirmed on August 6, 2021 at 10:35 a.m., that the laboratory failed to follow manufacturer's instructions to perform Covid Ag by Id Now system.. 5. The laboratoty reported and performed 312 patient's specimens for Covid 19Ag tests in 2020 and 801 patient's specimens for Covid 19Ag tests since January 2021 by Id Now system.</p>
D5014	<p>GENERAL IMMUNOLOGY CFR(s): 493.1208</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.

This CONDITION is not met as evidenced by:
Based on Mycoplasma Pneumoniae quality control records review (2020-2021) and interview with the laboratory director on August 6, 2021 at 10: 00 AM, it was determined that the laboratory failed to meet the requirements in the subspecialty of General Immunology. The finding includes: a. The laboratory did not include an external positive and a negative control material each day of patient testing when performed M.Pneumoniae test. Refer to D 5449

D5020

ENDOCRINOLOGY
CFR(s): 493.1212

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.

This CONDITION is not met as evidenced by:
Based on serum Human Chorionic Gonadotropin (hCG) test quality control records (years 2020-2021) and interview with the laboratory director on August 6, 2021 at 9: 45 AM, it was determined that the laboratory failed to ensure compliance with the analytic system requirements for serum hCG qualitative tests. The finding includes: 1. 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

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 endocrinology quality control records review (2020-2021) and interview with the laboratory director on August 6, 2021 at 9:45 AM , it was determined that the laboratory failed to include a negative and positive control material when performed hCG test. The findings include : a. The laboratory performed hCG (human chorionic gonadotropin) by Instant view one step method. b. Endocrinology quality control logs were reviewed from 1/2020 to 08/2021. c. The records showed that the laboratory did not include a negative and positive control material from April 14, 2021 to July 30, 2021. d. The laboratory performed and reported 12 patient samples the following days: 4/14/21, 5/3/21, 5/21/21, 6/17/21, 6/30/17, 7/1/21, 7/12/21, 7/13/21, 7/19/21,7/19 /21 and 7/30/21. e. The laboratory director confirmed on August 6, 2021 at 9:50 A.M., that the laboratory failed to include a negative and positive control material each day

	<p>of testing when performed hCG test. 2. Based on General Immunology (Mycoplasma Pneumoniae test) quality control records review (2020-2021) and interview with the laboratory director on August 6, 2021 at 10:00 AM , it was determined that the laboratory failed to include a negative and positive control material when performed Mycoplasma Pneumoniae test by Immuno Card method. The findings include : a. The laboratory performed Mycoplasma Pneumoniae test by Immuno Card method. b. Mycoplasma quality control logs were reviewed from 4/2020 to 08/2021. c. The records showed that the laboratory did not include a negative and positive control material from April 20, 2021 to July 19, 2021. d. The laboratory performed and reported 8 patient samples the following days: 4/20/21, 6/22/21, 7/9/21, 7/12/21, 7/16/21, 7/17/21 and 7/19/21. e. The laboratory director confirmed on August 6, 2021 at 10:00 A.M., that the laboratory failed to include a negative and positive control material each day of testing when performed Mycoplasma Pneumoniae test by Immuno Card method.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on endocrinology , general immunology quality control records review (2020-2021) and laboratory director interview on August 6, 2021 at 11:30 AM, it was determined that the laboratory 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 D6020</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 quality control records review and laboratory director interview on August 6, 2021 at 11:30 AM, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. The finding includes : 1. The laboratory failed to include a negative and positive control material when performed hCG test and Mycoplasma Pneumoniae test. Refer to D5449.</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</p>

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 quality control records review and laboratory director interview on August 6, 2021 at 11:30 AM, it was determined that testing personnel failed to follow quality control procedures. Refer to D5449.