

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D0952483	<b>(X3) Date Survey Completed</b>  04/22/2021
<b>Name of Provider or Supplier</b>  Laboratorio Clinico Central Ii	<b>Street Address, City, State</b>  Ave Font Martelo # 350, Humacao, PR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5014</b>	<p><b>GENERAL IMMUNOLOGY</b> 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 general immunology (Covid 19 IgG/IgM) quality control records (from October 14, 2020 to April 21, 2021) review and laboratory testing personnel interview on April 22, 2021 at 10:30 AM, it was determined that the laboratory failed to ensure compliance with the analytic system requirements of General immunology. The finding includes: 1. The laboratory did not include each day of testing a negative and a positives control materials when patients serum specimens were tested for qualitative Covid 19 IgG/IgM by the Clarity Coviblock method. Refer to D 5449.</p>
<b>D5449</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on general immunology quality control records review (from October 14, 2020 to April 21, 2021) and laboratory testing personnel interview on April 22, 2021 at 10:30 AM, it was determined that the laboratory failed to include each day of testing a</p>

negative and a positive control materials when 34 out of 37 days when patients specimens were tested and reported for qualitative Covid 19 IgG / IgM tests from October 14, 2020 to April 21, 2021 by the Clarity Coviblock method. The findings include: 1. The laboratory uses Clarity Coviblock method to perform Covid 19 IgG /IgM patient's samples tests. 2. On April 22, 2020 at 10:30 AM, the general immunology quality control records showed that the laboratory did not include each day of testing the negative nor the positive control materials from October 14, 2020 to April 21, 2021. 3. The laboratory does not include the negative and a positive control material in the following days: Date # patient's samples 10/14/2020 1 10/15/2020 1 10/20/2020 2 10/21/2020 1 10/27/2020 1 10/30/2020 1 11/3/2020 2 11/6/2020 2 11/7/2020 4 11/10/2020 1 11/12/2020 2 11/16/2020 3 11/17/2020 1 11/20/2020 4 11/23/2020 2 12/1/2020 1 12/3/2020 1 12/4/2020 2 12/5/2020 1 12/8/2020 1 12/15/2020 2 12/17/2020 7 1/7/2021 3 1/13/2021 1 1/14/2021 1 1/20/2021 1 1/25/2021 1 2/2/2021 1 3/1/2021 2 3/10/2021 1 3/19/2021 1 3/26/2021 1 3/30/2021 1 4/8/2021 1 4/9/2021 2 4. The laboratory testing personnel on April 22, 2021 at 10:30 AM, confirmed that the laboratory did not include the negative not the positive control materials each day testing from October 14, 2020 to April 21, 2021. 4. The laboratory processed and reported sixty (60) patient's specimens for qualitative Covid 19 IgG/IgM tests from October 14, 2020 to April 21, 2021 by the Clarity Coviblock method.

**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 quality control records (from October 14, 2020 to April 21, 2021), manufacturer's instructions review and testing personnel interview on April 22, 2021 at 10:30 AM, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory analytical system and quality assessment requirements. The finding includes: 1. The laboratory director did not comply with the requirement for analytical systems. Refer to D 6020.

**D6020**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(5)

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.

This STANDARD is not met as evidenced by:  
Based on general immunology quality control records review (from October 14, 2020 to April 21, 2021) and laboratory testing personnel interview on April 22, 2021 at 10:30 AM, it was determined that the laboratory director to ensure compliance with the requirements for analytic systems. Refer to D5449. The finding includes: 1. The

laboratory failed to include each day of testing a negative and a positive control materials when 34 out of 37 days when patients specimens were tested and reported for qualitative Covid 19 IgG / IgM tests from October 14, 2020 to April 21, 2021 by the Clarity Coviblock method.

**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 general immunology quality control records review (from October 14, 2020 to April 21, 2021) and laboratory testing personnel interview on April 22, 2021 at 10:30 AM, it was determined that testing personnel failed to follow quality control procedures. Refer to D5449. The finding includes: 1. The laboratory failed to include each day of testing a negative and a positive control materials when 34 out of 37 days when patients specimens were tested and reported for qualitative Covid 19 IgG / IgM tests from October 14, 2020 to April 21, 2021 by the Clarity Coviblock method.