

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658041	(X3) Date Survey Completed 07/08/2021
Name of Provider or Supplier Laboratorio Clinico Borinquen-Bairoa	Street Address, City, State Centro Comercial Bairoa, Caguas, 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
D5551	<p>IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f)</p> <p>(a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on ABO, Rh group and indirect quality control and testing records review (Years 2020 and 2021) and testing personnel interview on July 8, 2021 at 11:15 AM, it was determined that the laboratory failed to follow quality control procedures when 3 out 310 patient's specimens were tested for ABO, Rh group and indirect coomb's during the year 2020. The findings include: 1. On July 8, 2021 at 11:15 AM, the ABO, Rh group and indirect quality control and testing records showed that the laboratory did not perform the quality control procedures when the following patients specimens were tested and reported: Patients Tests Date processed Number and reported a. 798147 ABO,Rh and June 27, 2020. Indirect Coombs b. 027067 ABO, Rh December 3, 2020 c. 710371 ABO,Rh and December 3, 2020 Indirect Coombs 2. The testing personnel confirmed on July 8, 2021 at 11:15 AM, the laboratory did not recorded the quality control procedures those days. 3. The laboratory processed and reported 310 patients specimen in the Immunohematology area during the year 2020.</p>
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 ABO, Rh group and indirect quality control and testing records review (Years 2020 and 2021) and testing personnel interview on July 8, 2021 at 11:15 AM, it was determined that the laboratory director failed to ensure compliance with the requirements for Immunohematology tests during the year 2020. The finding includes: 1. . The laboratory director did not ensure that the quality control procedures were performed each days of ABO, Rh group and indirect coomb's testing during the year 2020. Refer to D 5551.

D6117

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(4)

The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results.

This STANDARD is not met as evidenced by:

Based on ABO, Rh group and indirect quality control and testing records review (Years 2020 and 2021) and testing personnel interview on July 8, 2021 at 11:15 AM, it was determined that the technical supervisor did not assure that the quality control procedures in the Immunohematology area were performed each day of testing during the year 2020. The finding includes: 1. . The laboratory did not follow quality control procedures when 3 out 310 patient's specimens were tested for ABO, Rh group and indirect coomb's during the year 2020. Refer to D 5551