

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 40D0667819	<b>(X3) Date Survey Completed</b> 07/26/2023
<b>Name of Provider or Supplier</b> Pr Clinical Reference Laboratory	<b>Street Address, City, State</b> Jose J Acosta 46, Vega Baja, 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>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on ABO and Rh reactivity quality control record review, patient worksheet records and interview with the laboratory supervisor on July 26, 2023 at 2:30 PM; it was determined that the laboratory performed 370 out of 370 ABO test in patient's sample with Cells A by Immucor that exceeded the expiration date. The findings include: 1. The laboratory perform ABO in the Immunohematology specialty. 2. On July 26, 2023 at 1:03 PM the reactivity quality control record of cells by Immucor was reviewed and showed Cells A (lot. #111400) with expiration date of May 13, 2022. The next new Cells A (lot. #111408) with expiration date of June 8, 2022 was opened on June 8, 2022. 3. On July 26, 2023 at 1:15 PM the patient worksheet record was reviewed from May 14, 2022 to June 8, 2022 and showed that the laboratory did not document if any new lot of Cells A was open between May 14, 2022 to June 8, 2022. 4. On July 26, 2023 at 2:30 PM the laboratory supervisor confirmed that the laboratory used a expired Cells A to perform and process the ABO test in 370 out 370 patient's sample from May 14, 2023 to June 8, 2022.</p>
<b>D6093</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>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.</p>

This STANDARD is not met as evidenced by:  
Based on ABO and Rh reactivity quality control record review, patient worksheet records and interview with the laboratory supervisor on July 26, 2023 at 2:30 PM; it was determined that the laboratory director failed to ensure the compliance with the quality control program when the laboratory performed 370 out of 370 ABO test in patient's sample with Cells A by Immucor that exceeded the expiration date. Refer to D5417