

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0670646	(X3) Date Survey Completed 10/22/2021
Name of Provider or Supplier Laboratorio Clinico Jardines Corp	Street Address, City, State Jardines De Cntry Club Be-S Calle 101, 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
D5417	<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 Immunohematology control records review and laboratory general supervisor interview on October 22, 2021 at 10: 18 AM. , It was determined that the laboratory used Screaming Cells I, Screening Cells II and Coombs Control Cells, controls materials that have exceeded their expiration date. The findings include: 1. Review of Immunohematology quality control records showed that laboratory used Screening Cells I (lot: S254 exp march 30, 2021), The Screening Cells II (lot: S254 exp march 30, 2021), Coombs Control Cells (lot: K713 exp. march 30,2021) from March 31, 2021 to April 7, 2021. 3. From March 31, 2021 to April 7, 2021 the laboratory processed and reported five patient samples. 4. The laboratory supervisor confirmed on October 22, 2021 at 10:18 AM that the laboratory used expired control material and they tested and reported five out of five patient samples.</p>
D6093	<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> <p>This STANDARD is not met as evidenced by:</p>

Based on Immunohematology quality control records review and laboratory director interview on October 22, 2021 at 10:18 AM, it was determined that the laboratory director failed to comply with the analytic system requirements. Refer D 5417.