

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0909061	(X3) Date Survey Completed 01/20/2023
Name of Provider or Supplier Laboratorio Clinico La Providencia	Street Address, City, State Carr #132 Km 24 Hm 3, Ponce, 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 culture media record review (year 2022), patient worksheet records (year 2022) and interview with the laboratory supervisor on January 20, 2023 at 12:38 PM; it was determined that the laboratory processed one out of one stool culture with a MacConkey Sorbitol media that exceeded the expiration date. The findings include: 1. The laboratory perform stool culture in the Bacteriology specialty. 2. On January 20, 2023 at 12:20 PM the record of culture media showed that the MacCkonkey sorbitol media Lot # 429863 expired on April 5, 2022. The next new lot was received on April 18, 2022. 3. On January 20, 2023 at 12:35 PM the patient worksheet record was reviewed from April 5, 2022 to April 18, 2022 and showed that the laboratory used a MacConkey Sorbitol expired culture media to perform and process a stool culture for one patient sample (patient no. 001526) on April 12, 2022. 4. On January 20, 2023 at 12:38 PM the laboratory supervisor confirmed that the laboratory used a expired culture media to perform and process a stool culture for one out of one patient on April 12, 2022.</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>

This STANDARD is not met as evidenced by:
Based on Bacteriology specialty culture of media records review (year 2022), patients worksheet record review and interview with the laboratory supervisor, it was determined that the laboratory director failed to ensure the quality control for stool culture media. Refer to D5417