

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0708759	(X3) Date Survey Completed 01/25/2023
Name of Provider or Supplier Labclinico Y Bacteriologico Torval Agostini	Street Address, City, State Calle Santiago R Palmer #21, Cidra, 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, patient worksheet records and interview with the laboratory director and laboratory general supervisor; it was determined that the laboratory performed three (3) out of three (3) urine culture with a Blood Agar that exceeded the expiration date. The findings include: 1. The laboratory perform Urine culture in the Bacteriology specialty. 2. On January 25, 2023 at 11:35 AM the record of culture media was reviewed and showed a Blood Agar Lot # 463234 with expiration date of May 31, 2022. The next new lot was received on June 7, 2022. 3. On January 25, 2023 at 11:40 AM the patient worksheet record were reviewed from May 31, 2022 to June 7, 2022, showing that the laboratory used the expired culture media to perform and process urine cultures for three (3) patient's. 4. On January 25, 2023 at 12:05 PM the laboratory director and laboratory supervisor confirmed that the laboratory used expired culture media to perform and process urine culture for three (3) out of three (3) patient's.</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 director and laboratory supervisor; it was determined that the laboratory director failed to ensure that the culture media not exceed the expiration date. Refer to D5417.