

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 40D0672862	<b>(X3) Date Survey Completed</b> 01/27/2023
<b>Name of Provider or Supplier</b> Lab Clinico Fernando Montilla Inc	<b>Street Address, City, State</b> 401 Fernando Montilla Street, San Juan, 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 direct observation at the laboratory sample collection area, samples referral records review and laboratory testing personnel interview; it was determined that the laboratory failed to used supplies for the sample collection procedures that have exceeded their expiration date. The findings include: 1. The laboratory had one sample collection station. On January 27, 2023 at 12:02 PM, the sample collection station had in use 6 yellow top tubes that have exceeded their expiration date: Lot C01005, Exp. 04/2022. 2. On January 27, 2023 at 12:08 PM the patient's sample referral records showed, that 15 patient's specimens were referred. Observation of the test tubes stored in the laboratory refrigerator showed that the sample collection tubes had an expiration date of April 2022. 3. The laboratory testing personnel confirmed on January 27, 2023 at 12:08 PM, that the laboratory used 15 expired sample collection tubes from January 20, 2023 to January 27, 2023.</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> <p>This STANDARD is not met as evidenced by:</p>

Based on direct observation at the laboratory sample collection area, samples referral records and laboratory testing personnel interview; it was determined that the laboratory director failed to ensure the integrity of the patient samples. The laboratory used expired sample collection tubes during January 2023. Refer to D5417