

<p>Statement of Deficiencies</p>	<p>(X1) Provider/Supplier/CLIA Identification Number</p> <p>66D0662224</p>	<p>(X3) Date Survey Completed</p> <p>04/27/2023</p>
<p>Name of Provider or Supplier</p> <p>Commonwealth Health Ctr - Laboratory</p>	<p>Street Address, City, State</p> <p>1178 Hinemu' St Garapan, Saipan Mariana Islands, MP</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p>(X4) ID Prefix Tag</p>	<p>Summary Statement of Deficiencies</p>
<p>D5417</p>	<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 and laboratory testing personnel interview on April 24, 2023 at 10:12 am, it was determined that the laboratory failed to ensure that all reagents were not available for use when they have exceeded their expiration date. Findings include: a. During a tour of the Microbiology section of the laboratory, it was observed that Gram stain reagent, BBL Gram Iodine, Lot #1145691, had an expiration date of December 31, 2022, which was found among other Gram stain reagents used for patient testing that were available for use in patient testing. b. The laboratory personnel and manager confirmed that the Gram Iodine reagent was available for use when it had exceeded its expiration date. c. According to laboratory personnel, the laboratory performs approximately 108 Gram stains on patient specimens annually.</p>