

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 40D0658266	<b>(X3) Date Survey Completed</b> 02/17/2023
<b>Name of Provider or Supplier</b> Hato Rey Pathology Associates	<b>Street Address, City, State</b> Avenida Domenech 300,302,304,306, Hato Rey, 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 Cytology inventory of chemical reagent and interview with the laboratory staff; it was determined that the laboratory performed 5,986 out of 99,904 Thin prep staining process with a rinse solution that exceeded the expiration date from August 18, 2022 to September 6, 2022. The findings include: 1. The laboratory perform Thin Prep staining process in Cytology. 2. On February 17, 2023 at 9:42 AM, the record of cytology inventory of chemical reagents was reviewed. The Inventory showed that the laboratory used a rinse solution, lot # 1230CA that expired on August 8, 2022. The next new lot # 2041CA of rinse solution was received on September 6, 2022. 3. On February 17, 2023 at 10:07 AM, the laboratory patient record ,year 2022, showed that 5,986 patient's out of 99,904 patient's were processed with a rinse solution that exceeded the expiration date. 4. On February 17, 2023 at 10:25 AM the laboratory staff confirmed that the laboratory used a expired rinse solution to perform the Thin prep staining process in 5,986 patient's out of 99,904 patient's from August 8, 2022 to September 6, 2022.</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>

This STANDARD is not met as evidenced by:  
Based on Cytology inventory of chemical reagent and interview with the laboratory staff; it was determined that the laboratory director failed to ensure that the reagent that was in used did not exceed the expiration date when performed 5,986 out of 99,904 Thin prep staining process with a rinse solution that exceeded the expiration date from August 18, 2022 to September 6, 2022. Refer to D5417