

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658184	(X3) Date Survey Completed 08/30/2023
Name of Provider or Supplier Ponce Clinical Laboratory, Inc	Street Address, City, State 1128 Munoz Rivera Reparto Universidad, 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, patient worksheet records and interview with the laboratory supervisor on August 30, 2023 at ; it was determined that the laboratory performed 12 out of 12 urine culture with a Blood Agar that exceeded the expiration date. The findings include: 1. The laboratory perform colony count in urine culture in the bacteriology specialty. 2. On August 30, 2023 at 12:41 PM, the record of culture media was reviewed and showed the Blood Agar media Lot # 518272 with expiration date of September 16, 2022. Since September 17, 2022 the laboratory did not received nor document a new lot of Blood Agar media. 3. On August 30, 2023 at 12:46 PM, the patient worksheet record was reviewed and showed that the laboratory process colony count of urine culture from September 17, 2022 to October 16, 2022. From October 17, 2022 the laboratory refer the urine culture media to another laboratory. 4. On August 30, 2023 at 12:53 PM the laboratory supervisor confirmed that the laboratory used a expired culture media to perform the colony count of urine culture for 12 out of 12 patient's sample.</p>
D6020	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory</p>

director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on bacteriology quality control records review (year 2022 and 2023) and interview with the laboratory supervisor on August 30, 2023 at 12:53 P.M., it was determined that the laboratory director did not ensure that the laboratory use a blood agar media that did not exceed the expiration date. Refer to D5417.