

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2191982	(X3) Date Survey Completed 08/11/2022
Name of Provider or Supplier Princeton University Clinical Laboratory	Street Address, City, State Lewis Thomas Laboratory Washington Road, Princeton, NJ	
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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of RNaseZap RNase Decontamination Solution bottles and Chemagic reagent boxes, review of Storage Room Temperature Logs (SRTL) and interview with the General Supervisor (GS), the laboratory failed to follow the Instruction For Use (IFU) for Storage and Stability at the time of survey. The findings include: 1. The IFU stated acceptable storage temperatures were 15-25 degrees Celsius for RNaseZap RNase Decontamination Solution bottles but the SRTL had 18-30 degrees Celsius. 2. The IFU for Chemagic reagent boxes stated acceptable storage temperature range was 15-25 degrees Celsius but the SRTL had 15-32 degrees Celsius. 3. The GS confirmed on 8/11/22 at 12:50 pm that the laboratory did not follow the IFU.</p>