Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0990132	(X3) Date Survey Completed 03/16/2022
Name of Provider or Supplier Leonid Sorkin, Md	**Street Address, City, State** 2829 Ocean Parkway Suite C, Brooklyn, NY	

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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the laboratory's humidity logs from 1/1/2021 through survey date, the Beckman Dickinson manufacturer's specification the Access 2 analyzer and an interview with the technical consultant, the laboratory failed to take corrective action for the out-of-range humidity during the calendar year 2021. FINDINGS 1. Beckman Dickinson manufacturer requires a humidity range of 10-80% for the Access 2 analyzer. 2. The laboratory's humidity chart has an established range of 20%-75%. a. The humidity was out of range from 1/1/2021 through 3/11/21 with ranges recorded at 13% or 14% during this time. 3. The technical consultant confirmed on 3/16/22 at approximately 2:00 PM laboratory failed to take corrective action for the out-of-range humidity.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) 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.

	This STANDARD is not met as evidenced by: Based on direct observation of the KOH 10 bottle and an interview with the technical consultant, the laboratory failed to discard the expired bottle with expiration date of 3 /3/2020. FINDINGS: 1. The surveyor observed at 2:30 PM an bottle of 10% KOH with an expiration date of 3/3/2020 and Lot #1906307 next to the microscope. 2. The technical consultant confirmed on 3/16/2022 at approximately 2:30 PM the expired bottle of KOH.