Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2295302	04/09/2026
Name of Provider or Supplier	**Street Address, City, State**	
Ronald R Brancaccio, Md & Peter Saitta, Do, Pc	56850 Main Road, Suite #1, Southold, 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) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 equipment manufacturer's specifications, lack of Standard Operating Procedures (SOPs), as well interview with the Office Manager (OM), the laboratory failed to define criteria for those conditions that are consistent with manufacturer's instructions. FINDINGS: 1. The Avantik Cryostat Qs12 automatic stainer manufacturer's instructions specify 60% maximum humidity for operation conditions. 2. The Ronald Brancaccio, M.D. & Peter Saitta, D.O., PC SOPs did not include instructions for Avantik Cryostat Qs12 operation humidity range. 3. The OM confirmed the findings on April 9, 2026, at approximately 10:30 A.M.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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 observations, lack of SOPs, as well as interview with the OM, the laboratory failed to remove from inventory expired materials utilized in the Mohs processing laboratory. FINDINGS: 1. The surveyor's observations in the Mohs processing laboratory confirmed on April 9, 2026, at approximately 10:30 A.M., the following expired material was not removed from inventory: a. TFM-C Tissue Freezing Medium, lot: 175611, expiration: June 30, 2025, was stored in the cabinet above the cryostat Avantik Qs12 in the Mohs processing laboratory. 2. The Ronald Brancaccio, M.D. & Peter Saitta, D.O., PC SOPs did not include instructions for removal of expired reagents, supplies, and test kits from inventory. 3. The OM informed the surveyor on April 9, 2026, at approximately 10:30 A.M. that the expired material was utilized for patient specimen processing. Approximately 500 patient specimens were potentially processed utilizing the expired TFM-C Tissue Freezing Medium. 4. The OM confirmed the findings on April 9, 2026, at approximately 10:30 A.M.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on lack of equipment Preventative Maintenance (PM) records; review of SOPs and microscope manufacturer's instructions; as well as interview with the OM, the laboratory failed to perform maintenance as defined by the manufacturer with at least the frequency specified by the manufacturer. FINDINGS: 1. There was no documentation of Olympus CX 33 microscope PM performance since purchase in 2024. 2. This is contrary to instructions indicated in the Ronald Brancaccio, M.D. & Peter Saitta, D.O., PC SOPs as well as Olympus CX 33 manufacturer's instructions which specify annual microscope PM. 3. The OM confirmed the findings on April 9, 2026, at approximately 11:00 A.M.