Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2047462	01/28/2026
Name of Provider or Supplier	**Street Address, City, State**	
Jeffrey Laduca, Md Pc	7040 Manlius Center Rd, East Syracuse, 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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of waived testing manufacturer's package insert instructions, lack of Quality Control (QC) documentation, as well as interview with the Laboratory Directory (LD), the laboratory failed to follow manufacturer's instructions for performing waived testing. FINDINGS: 1. There was no documentation of QC performance for the First Sign One-Step Urine Pregnancy Test Strip kits, lot: D5240525; expiration: April 30, 2028. 2. There was no documentation of ambient room temperature for the area where the First Sign One-Step Urine Pregnancy Test Strip kits were stored, patient specimens processed, and testing performed. 3. These are contrary to instructions included in the First Sign One-Step Urine Pregnancy Test Strip test kit manufacturer's instructions which specified storage temperature range of 4C to 30C (40F to 86F). 4. The LD confirmed the findings on January 28, 2026, at approximately 1:30 P.M.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following:

	This STANDARD is not met as evidenced by: Based on review of patient test result records, laboratory Standard Operating Procedure (SOP) policies and procedures manual, as well as interview with the LD, the laboratory failed to retain documented patient test records for at least two years. FINDINGS: 1. There was no documentation of Potassium Hydroxide (KOH) and scabies patient test results for calendar years 2024 and 2025. 2. This is contrary to record retention instructions indicated in the current, approved laboratory SOP policies and procedures manual. 3. The LD confirmed the KOH and scabies patient test results for calendar years 2024 and 2025 were unaccounted for and not available for review on January 28, 2026, at approximately 1:30 P.M.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of SOP policies and procedures manual, lack of calibration records, as well as interview with the Histotechnician (HT), the laboratory failed to draft and approve requirements for calibration and calibration verification. FINDINGS: 1. There was no calibration documentation for the Acu-Rite digital thermometer and humidistat used to monitor the ambient room temperature and humidity in the Mohs laboratory. 2. The current, approved SOP policies and procedures manual did not include instructions for thermometer calibration and certificate retention. 3. The HT confirmed the findings on January 28, 2026, at approximately 12:40 P.M.
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 the laboratory SOP policies and procedures manual, test kit manufacturer's package inserts, lack of room temperature and humidity records, as well as interviews with the LD and HT, the laboratory failed to monitor and document conditions that were essential for proper storage of reagents and test kits, patient specimen processing, and patient testing. FINDINGS: 1. There was no documentation of ambient room temperature for the area where the Hardy Diagnostics KOH 10% test kits were stored, patient specimens processed, and testing performed. 2. The Hardy Diagnostics KOH 10%, lot: 677081, expiration: October 3, 2026, manufacturer's instructions specified storage temperature range of 2C to 30C. 3. No thermometer was present to monitor the ambient room temperature in the area where the Hardy Diagnostics KOH 10% kits were stored, patient specimens processed, and testing performed. 4. The current, approved laboratory SOP policies and procedures manual did not include instructions for performing such activity. 5. The LD and HT confirmed the findings on January 28, 2026, at approximately 1:30 P.M.