

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D1079223	(X3) Date Survey Completed 01/14/2026
Name of Provider or Supplier Cindy Hoffman Do Pc	Street Address, City, State 686 Stoneleigh Ave, Carmel, 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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of Standard Operating Procedures (SOPs), lack of calibration records, as well as interview with the Mohs Technician (MT), the laboratory failed to draft and approve procedures for thermometer and humidistat calibration. FINDINGS: 1. There was no calibration documentation or certificate of analysis for the thermometer and humidistat used to monitor the temperature and humidity in the Mohs processing laboratory. 2. The current, approved SOPs did not include instructions for thermometer and humidistat calibration and certificate retention. 3.</p>

While no thermometer or humidistat were present in the Mohs processing laboratory at the time of the survey, it was noted that ambient room temperature and humidity logs were available for review. 4. The MT confirmed the findings on January 14, 2026, at approximately 12:10 P.M.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on direct observations, review of SOPs, as well as interview with the MT, the laboratory failed to properly label reagents with identity, storage requirements, preparation, and expiration dates. FINDINGS: 1. The surveyor's observations in the Mohs processing laboratory on January 14, 2025, at approximately 1:25 P.M. confirmed the following reagents utilized by the Shandon Linistain Thermo Scientific automated stainer, SN: LS1372A1101, in the Mohs laboratory, were not labeled with identification, concentration, lot number, expiration date, and storage requirements: a. 95% Alcohol b. Water c. Hematoxylin + water d. Acid Alcohol e. Water f. Bluing (Scott's) g. Water h. 95% Alcohol i. Eosin j. 95% Alcohol k. 100% Alcohol l. Xylene substitute 2. The current, approved SOPs did not include instructions for performing such activities. 3. The MT confirmed the findings on January 14, 2026, at approximately 1:55 P.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, review of current, approved SOPs, as well as interview with the MT, 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 January 14, 2026, at approximately 1:15 P. M., the following expired material was not removed from inventory: a. Sakura Tissue-Tek O.C.T. compound, lot: 4834-00, expiration: June 30, 2025, was stored on the countertop in the Mohs processing laboratory. 2. The current SOPs did not include instructions for removal of expired reagents, supplies, and test kits from inventory. 3. The MT informed the surveyor that the expired material was utilized for patient specimen processing. Approximately one hundred ten patient specimens were potentially processed utilizing the expired Sakura Tissue-Tek O.C.T. compound. 4. The MT confirmed the findings on January 14, 2026, at approximately 1:55 P.M.