

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2329121	(X3) Date Survey Completed 03/04/2026
Name of Provider or Supplier Complexions Dermatology, Pc	Street Address, City, State 1900 Ashwood Ct, Greensboro, NC	
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
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i) (a)(3)(i) Records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: Based on review of 2025 and 2026 laboratory records, the absence of validation records, and interview with the laboratory director 3/4/26, the laboratory failed to retain validation documentation for the hematoxylin and eosin (H&E) staining performed. Review of 2025 and 2026 laboratory records revealed the laboratory did not have validation records for the H&E stains performed, including a summary /timeline of the steps taken to validate the H&E stain, the date patient testing began, and the laboratory director's signature and date of approval. During interview at approximately 11:05 a.m., the laboratory director stated the validation was done prior to the start of patient testing, but they could not locate it. He stated Mohs patient testing began 9/9/25.
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 the laboratory's policies and procedures and interview with the Mohs surgeon and the laboratory director 3/4/26, the laboratory's procedure manual was not complete and current for the testing performed. Examples: 1. Review of the laboratory's "Grossing Tissue" policy revealed "Grossing is done by Surgeon, Fellow, or Certified Histotech. ..." Review of the laboratory's "Test Procedure: Embedding" revealed "... The specimen is grossed by the mohs surgeon, fellow or certified histotech. ..." During interview at approximately 10:40 a.m., the Mohs surgeon stated that histotechs do not perform grossing in this laboratory. 2. Review of the laboratory's policies and procedures revealed a stain procedure "Toluidine Blue Protocol" which is not performed by the laboratory. During interview at approximately 10:50 a.m., the laboratory director confirmed the laboratory does not perform staining with toluidine blue. 3. Review of the laboratory's policies and procedures revealed the laboratory did not have a written policy which described the laboratory's process for reporting patient Mohs surgery test results in the electronic medical records system. The "Reading Results" policy stated "Microscopic: A detailed report will be included in the patient's electronic chart. It will include a description of the tumor, any unusual histological features and the location of any residual tumor that is remaining after each layer of tissue is removed. ..." The policy did not indicate how the results are reported or who is responsible. During interview at approximately 10:55 a.m., the laboratory director confirmed they did not have a detailed written policy for reporting patient Mohs surgery test results.