Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D2314103	02/13/2026
Name of Provider or Supplier	**Street Address, City, State**	
Vivaskin Dermatology And Aesthetics, Pllc	70 Hastings Street, Suite Ll-2, Wellesley, MA	

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
D0000	A CLIA initial survey was conducted for the Vivaskin Dermatology and Aesthetics, PLLC laboratory on 02/13/2026 pursuant to the Clinical Laboratory Improvement Act (CLIA) of 1988 and CLIA regulations at 42 CFR CFR 493.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on MOHS record review and staff interview with testing personnel (TP1) the laboratory failed to verify at least twice annually the accuracy of MOHS testing in the specialty of Histopathology. Findings include: 1. Record review on 02/13/2026 of the laboratory's MOHS Procedure manual revealed: a. The MOHS procedure manual was reviewed annually by the laboratory director (LD) in January of 2025 and February of 2026. b. The laboratory policy for pathology case review states "3 cases every 6 months" will be sent out for second review. 2. Record review of the MOHS surgeon case review records from January 2025 to date revealed: a. No cases were sent out for review in the year 2025. b. A case review sheet dated 2/ /2026 with three case numbers on it and no other information. 3. Staff interview with TP1 on 2/13/2026 at 11:00 AM confirmed the above findings. TP1 stated "We just sent slides out for review for the first time this month." 4. The laboratory runs 172 Histopathology tests annually.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and

	procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on record review and interview with testing personnel (TP1) the laboratory failed to perform ongoing quality assessment of its policies and procedures. Findings include: 1. Record review of the MOHS Procedure manual revealed the Laboratory Director (LD) reviewed and signed the manual annually in January 2025 and February 2026. 2. Review of the laboratory policy named Quality Assurance policy states "Monthly the nurse or tech will check off the Monthly Quality Assurance Checklist." "The lab director will also review and sign off this checklist monthly." 3. During interview on 2/12/2026 at 10:45 AM the surveyor asked TP1 for the monthly checklists. TP1 stated "we are not doing that." The laboratory performs 172 Histopathology tests annually.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on record review on and interview with testing personnel (TP1) on 2/13/2026 the laboratory failed to follow instructions for the cryostat performance specifications. Findings include: 1. Record review of the laboratory Cryostat policy states "According to manufacturer's instructions, lab personnel should oil weekly, grease monthly and/or perform necessary maintenance." 2. Review of Cryostat daily logs from 1/1/2026 to date did not indicate that weekly, monthly or necessary maintenance was performed. 3. Staff interview on 2/13/2026 at 10:30 AM confirmed this. TP1 stated the logs do not indicate which days weekly, monthly and preventative maintenance was done. The laboratory performs 172 Histopathology tests annually.
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 record review and interview with the Testing Personnel (TP1) the laboratory failed to monitor and record daily cryostat temperatures. Findings include: 1. Record

	review on 2/13/2026 of the Laboratory MOHS Cryostat Procedure states "Console temperature is recorded daily. The cryostat should be maintained at -20 *C to no colder than -30* C for best MOHS sectioning." 2. Record review of the 2025 and 2026 Cryostat daily checklist revealed no temperatures were recorded from 1/1/2025 to date. 3. Staff interview with TP1 on 2/13/2026 at 10:30AM TP1 stated "we do not write down the temperature daily." The laboratory performs 172 Histopathology tests annually.