Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2302338	03/17/2025
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Partners Sparks	10 Fila Way Suite 205, Sparks, MD	

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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: I. Based on procedure manual and daily maintenance log record review and interview with the Director of Training and Compliance (DTC), the laboratory failed to follow written procedures for documenting the laboratory director's (LD) review of daily maintenance. Findings: 1. The procedure, "Laboratory Daily Maintenance" states, "The laboratory director will personally document that all daily maintenance has been completed by initialing daily maintenance log on every day that the laboratory is used for patient testing." 2. A review of "Daily Laboratory Maintenance" logs from June 2024 through February 2025 showed that the histotechnician (HT) initialed the daily maintenance log on each day of patient testing, not the LD. 3. During an interview on 03/17/2025 at 11:20 AM, the DTC stated that the procedure manual was incorrect, and that the HT was supposed to initial the daily maintenance logs. They confirmed that the laboratory failed to follow the procedures as written. II. Based on procedure manual and quality assurance (QA) record review, and interview with the Director of Training and Compliance (DTC), the laboratory failed to follow written procedures for performing monthly QA reviews. Findings: 1. The procedure, "Quality Assurance Policy" states, "Monthly, the nurse or Mohs histotech, along with the laboratory director, will check off the line items on the Monthly Quality Assurance Checklist" and "The lab director or their assigned designee will be responsible for signing off on this checklist on a monthly basis." The procedure did not state that the QA reviews were not to be performed if there was no testing done during the month. 2. A review of "Monthly Quality Assurance Checklists" from June 2024 through February 2025

	showed that there were no monthly QA checklists available at the time of the survey for three of nine months (July and September 2024 and January 2025) when the laboratory had not performed histopathology testing. 3. During an interview on 03/17 /2025 at 11:45 AM, the DTC confirmed that the laboratory failed to follow QA procedures as written in the procedure manual.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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 procedure manual review, surveyor observation, and interview with the Director of Training and Compliance (DTC), the laboratory failed to document the lot numbers and expiration dates of reagents used for histopathology testing, ensuring that they were not used when they had exceeded their expiration date, had deteriorated, or were of substandard quality. Findings: 1. The laboratory performs histopathology testing on patient specimens from Mohs surgery. 2. The procedure, "Quality Assurance for Routine Stains" states "All reagents and supplies used in the lab will be documented upon opening and put in use. This will consist of open date, lot number, expiration date." 3. During a tour of the laboratory on 03/17/2025 at 10:00 AM, it was observed that the laboratory stored their histopathology stain reagents in a flammable storage cabinet. During an interview, the DTC stated that the laboratory did not document the lot numbers and expiration dates of reagents used for histopathology testing. 4. The bottles of opened reagents observed were as follows: "UltraClear" (lot # 2335406, expiration date: 12/25/2025); "Bluing Reagent" (lot # 190680, expiration date: 02/28/2027); "Gill 3 Hematoxylin" (lot # 203264, expiration date: 01/31/2026); "Eosin Working Solution" (lot # 44010010, expiration date: 01/29 /2026); "Alcohol 100%" (lot # 2424301, expiration date: 09/03/2027); and "Alcohol 95%" (lot # 231213-B073133, expiration date: 12/03/2026). 5. During an interview on 03/17/2025 at 11:45 PM, the DTC confirmed that the laboratory failed to document the lot numbers and expiration dates of reagents used for histopathology testing.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on quality control (QC) and patient log record review and interview with the Director of Training and Compliance (DTC), the laboratory failed to ensure that daily stain QC was consistently documented, recording the quality of the staining characteristics of the Hematoxylin and Eosin (H&E) stain each day of patient testing. Findings: 1. The laboratory performs H&E staining procedures to evaluate histopathology slides. Daily stain QC for the H&E stain is recorded on the "Quality

	Control Staining - H & E Staining Only" log. 2. A review of daily stain QC logs from seven days of testing from 06/07/2024 to 02/27/2025 showed that on two of seven days the results of the stain QC was not documented on the "Quality Control Staining - H & E Staining Only" log; and 3. A review of patient logs showed that on those two days there were four patients tested on 08/20/2024 (case # SA024-24 through case # SA027-24) and nine patients tested on 10/07/2024 (case # SA028-24 through case # SA036-24). 4. During an interview on 03/17/2025 at 11:45 AM, the DTC confirmed that daily stain QC was not consistently documented.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a review of Mohs maps and interview with the Director of Training and Compliance (DTC), the laboratory failed to ensure that the final test report included the name and address of the laboratory where histopathology slides were interpreted. Findings: 1. The laboratory began performing histopathology testing on patient specimens from Mohs surgery on 06/07/2024. 2. During an interview on 03/17/2025 at 11:40 AM, the DTC stated that the laboratory considers the patients' Mohs maps to be the final patient report. 3. Random review of Mohs maps (final reports) from two patients showed that for case # SA024-24 and case # SA003-25 the address of the laboratory on the Mohs map (final report) was incorrect. 4. During an interview on 03 /17/2025 at 11:45 AM, the DTC stated that the laboratory staff used a different provider's Mohs map and confirmed that the final reports did not include the correct address of the laboratory where the testing was performed.