Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0673424	02/10/2026
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Physicians Inc	208 West Main St, Ephrata, PA	

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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on lack of documentation, record review, and interview with the Lab Supervisor (LS), the laboratory failed to follow established specimen processing policies and procedures for 127 of 263 dermatopathology microscopic examinations performed from 09/04/2025 to 02/10/2026. Findings include: 1. The laboratory's Mohs Procedure stated "The specimen will be logged into the Mohs accession log. Logging requires an accession number, name, date, case number, site, diagnosis and stage." 2. On the day of survey, 02/10/2026 at 11:19 am, review of the laboratory's accession logs revealed the laboratory failed to document the following information for 127 of 263 specimens performed from 09/04/2025 to 02/10/2026: - Date 3. The LS confirmed the above findings on 02/10/2026 at 12:00 pm.
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 observation in the laboratory, review of laboratory temperature records, and interview with the Lab Supervisor (LS), the laboratory failed to monitor and document temperatures to ensure proper storage of reagents used for staining dermatopathology microscopic slides for 139 of 159 days from 09/04/2025 to 02/10 /2026 when testing personnel were not present in the laboratory. Findings include: 1. On the day of survey, 02/10/2026 at 9:38 am, during the tour of the laboratory, the surveyor observed the following reagents stored at room temperature used in the laboratory: - 1 bottle Statlab Statfreeze. Manufacturer storage requirements: less than 50C. 2. Review of the laboratory's temperature records revealed the laboratory failed to monitor and document room temperatures for 139 of 159 days from 09/04/2025 to 02/10/2026 when testing personnel were not present in the laboratory. 3. The LS confirmed the above findings on 02/10/2026 at 12:00 pm.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview with the Lab Supervisor (LS), the laboratory failed to establish and maintain a maintenance /function check policy for 1 of 1 thermometer used to ensure acceptable storage and operating temperatures were met in the laboratory for dermatopathology and mycology testing performed from 09/04/2025 to 02/10/2026. Findings include: 1. On the day of survey, 02/10/2026 at 10:06 am, the surveyor observed the following thermometer used in the laboratory to monitor the storage temperatures of reagents and supplies: - Black room temperature/humidity thermometer, manufacturer not indicated. 2. Review of laboratory procedures revealed the laboratory failed to establish and maintain a maintenance/function check policy for 1 of 1 thermometer used to ensure acceptable storage and operating temperatures were met in the laboratory for dermatopathology and mycology testing performed from 09/04/2025 to 02/10/2026. 3. The LS confirmed the above findings on 02/10/2026 at 12:00 pm.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on lack of documentation, review of laboratory records, and interview with the

	Lab Supervisor (LS), the laboratory failed to document the positive and negative control each day of patient testing for 4 of 4 mycology (KOH) microscopic examinations performed from 09/04/2025 to 02/10/2026. Findings include: 1. On the day of survey, 02/10/2026 at 10:15 am, review of KOH testing logs revealed the laboratory failed to document the positive and negative controls each day of use for 4 of 4 mycology (KOH) microscopic examinations performed from 09/04/2025 to 02/10 /2026. 2. Review of the laboratory's procedures revealed the laboratory failed to include the following in the laboratory's quality control procedures: - Type - Identity - Number and frequency of testing controls - Criteria to determine acceptable results 3. The laboratory performed 4 KOH slide examinations in 2025 (CMS 116, estimated annual volume, dated 01/22/2026). 4. The LS confirmed the above findings on 02/10 /2026 at 12:00 pm.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. This STANDARD is not met as evidenced by: Based on lack of documentation, review of laboratory procedures, and interview with the Lab Supervisor (LS), the laboratory failed to document a control slide of known reactivity to ensure acceptable staining characteristics of the Hematoxylin & Eosin (H&E) stains for 13 of 33 days when dermatopathology microscopic slides were examined from 09/04/2025 to 02/10/2026. Findings Include: 1. The laboratory's Quality Assurance: Routine Stains procedure stated, "A quality control slide will be run each day when the lab operates. The QC (quality control) slide will be for Hematoxylin and Eosin. The Mohs Surgeon will determine whether the stain is acceptable for the day. Each QC will be logged on the stain QC chart." 2. On the day of survey, 02/10/2026 at 9:38 am, the laboratory failed to provide documentation for the control slide of known reactivity performed for the following 13 of 33 days to ensure acceptable H&E staining characteristics when dermatopathology microscopic slides were examined from 09/04/202 to 02/10/2026: - 9/8/2025, 9/15/2025, 9/22 /2025, 9/29/2025, 10/06/2025, 10/13/2025, 10/20/2025, 10/27/2025, 11/03/2025, 11/10 /2025, 11/17/2025, 11/24/2025, 12/01/2025. 3. The laboratory performed 350 dermatopathology slide examinations in 2025 (CMS 116, estimated annual volume, dated 01/22/2026). 4. The LS confirmed the above findings on 02/10/2026 at 12:00 pm.
D5803	TEST REPORT CFR(s): 493.1291(b) (b) Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Lab Supervisor (LS), the laboratory failed to provide 1 of 1 patient test reports for mycology (KOH)

	examinations performed from 09/04/2025 to 02/10/2026, upon request of the surveyor. Findings Include: 1. On the day of survey, 02/10/2026 at 10:15 am, the laboratory failed to provide 1 of 1 patient test reports for mycology (KOH) examinations performed from 09/04/2025 to 02/10/2026, upon request of the surveyor. 2. The laboratory performed 4 KOH slide examinations in 2025 (CMS 116, estimated annual volume, dated 01/22/2026). 3. The LS confirmed the above findings on 02/10/2026 at 12:00 pm.
D5805	TEST REPORT CFR(s): 493.1291(c) (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 review of patient test reports (Mohs maps) and interview with the Lab Supervisor (LS), the laboratory failed to include the address of the location where dermatopathology microscopic (Mohs) slide examinations were performed on 2 of 2 patient test reports reviewed from 09/04/2025 to 02/10/2026. Findings Include: 1. On the day of survey, 02/10/2026 at 10:00 am, review of 2 of 2 patient test reports (Mohs maps) revealed the laboratory failed to include the address of the laboratory where Mohs slide examinations were examined from 09/04/2025 to 02/10/2026. 2. The laboratory performed 350 Mohs slide examinations in 2025 (CMS 116, estimated annual volume, dated 01/22/2026). 3. The LS confirmed the above findings on 02/10 /2026 at 12:00 pm.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview with the Lab Supervisor (LS), the Laboratory Director (LD) failed to ensure a Quality Assurance (QA) program was maintained and documented to assure the quality of services provided for 4 of 4 months from 09/04/2025 to 02/10/2026. Findings include: 1. The Laboratory's Quality Assurance Program procedure stated, "Laboratory Director will hold monthly staff meetings. Minutes should be taken and retained as documentation. All documentation must be signed by the Laboratory Director." 2. On the day of survey, 02/10/2026 at 10:06 am, review of the laboratory's monthly QA checklists revealed the laboratory director failed to review monthly documentation for the QA evaluation performed to assess the laboratory's pre-analytical, analytical, and post-analytical processes for the following 4 of 4 months from 09/04/2025 to 02/10/2026: -

	9/2025, 10/2025, 11/2025, 12/2025. 3. The laboratory failed to provide documentation for the monthly staff meetings held by the LD from 09/04/2025 to 02/10/2026. 4. The LS confirmed the above findings on 02/10/2026 at 12:00 pm.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) (e)(12) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Lab Supervisor (LS), the Laboratory Director (LD) failed to ensure 1 of 1 Testing Personnel (TP) received the appropriate training and demonstrated they can perform all testing operations reliably prior to testing dermatopathology specimens from 09/04/2025 to 02/10/2026. Findings Include: 1. On the day of the survey, 02/10/2026 at 9:45 am, the laboratory failed to provide training records for 1 of 1 TP (CMS 209 personnel #3, dated 01/22/2026) who performed dermatopathology microscopic examinations from 09/04/2025 to 02/10 /2026. 2. The laboratory performed 350 dermatopathology slide examinations in 2025 (CMS 116, estimated annual volume, dated 01/22/2026). 3. The LS confirmed the above findings on 02/10/2026 at 12:00 pm.