

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 39D2303427	<b>(X3) Date Survey Completed</b> 01/15/2026
<b>Name of Provider or Supplier</b> Dermatology Partners - Hanover	<b>Street Address, City, State</b> 250 Fame Ave, Suite 205, Hanover, PA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A recertification survey was conducted by the Pennsylvania State Agency at Dermatology Partners - Hanover on 01/15/2026. The laboratory was found out of compliance with the following condition: 493.1441 Condition: Laboratories performing high complexity testing; laboratory director.
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following:</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation, and interview with the Senior Director of Clinical Development (SDCD), the laboratory failed to retain analytic systems records for 3 of 15 months as required from 10/23/2024 to 01/15/2026. Findings include: 1. On the day of survey, 01/15/2026 at 9:38 am, the laboratory failed to provide documentation of the following analytic system records for 3 of 15 months from 10/23/2024 to 01/15/2026: - October 2024, November 2024, December 2024 Temperature logs - October 2024, November 2024, December 2024 Maintenance logs 2. The SDCD confirmed the above findings on 1/15/2026 at 11:35 am.</p>
<b>D5205</b>	<p><b>COMPLAINT INVESTIGATIONS</b> CFR(s): 493.1233</p> <p>The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.</p>

This STANDARD is not met as evidenced by:  
Based on lack of documentation and interview with the Senior Director of Clinical Development (SDCD), the laboratory failed to establish and maintain a policy to ensure all complaints and problems reported to the laboratory are documented and investigated when needed for 15 of 15 months from 10/23/2024 to 01/15/2026. Findings include: 1. On the day of survey, 01/15/2026 at 9:38 am, the laboratory could not provide a policy to ensure all complaints and problems reported to the laboratory were documented and investigated as needed for 15 of 15 months from 10/23/2024 to 01/15/2026. 2. The SDCD confirmed the above findings on 1/15/2026 at 11:35 am.

**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 record review and interview with the Senior Director of Clinical Development (SDCD), the laboratory failed to follow established specimen processing policies and procedures for 21 of 467 dermatopathology microscopic examinations performed from 10/23/2024 to 01/15/2026. Findings include: 1. The laboratory's Laboratory Procedure stated "The specimen is given an accession number and logged in the Mohs logbook. Patient name, date, site, diagnosis, stage or layer and number of quadrants per specimen layer." 2. On the day of survey, 01/15/2026 at 9:38 am, review of the laboratory's accession logs revealed the laboratory failed to document the following information for 21 of 467 specimens: - Date - Surgical site - Sections per stage 3. The SDCD confirmed the above findings on 1/15/2026 at 11:35 am.

**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 Senior Director of Clinical Development (SDCD), the laboratory failed to monitor temperatures to ensure acceptable reagent storage conditions were

maintained when the laboratory was closed for 434 of 449 days from 10/23/2024 to 01/15/2026. Findings include: 1. On the day of survey, 01/15/2026, at 10:35 am, during the tour of the laboratory, the surveyor observed the following reagents stored in the laboratory: - Avantik Embedding Matrix for Frozen Sections, storage requirements 39 to 86 F. 2. Review of the laboratory's temperature records revealed the laboratory failed to monitor and document temperatures to ensure acceptable reagent storage conditions were maintained for 434 of 449 days from 10/23/2024 to 01/15/2026 when the laboratory was closed. 3. The laboratory performed 350 dermatopathology microscopic examinations in 2025 (CMS 116, estimated annual volume, dated 01/14/2026). 4. The SDCD confirmed the above findings on 1/15/2026 at 11:35 am.

**D5431**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(a)(2)

(a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following:

This STANDARD is not met as evidenced by:  
Based on record review, lack of documentation, and interview with the Senior Director of Clinical Development (SDCD), the laboratory failed to ensure all laboratory established maintenance procedures were performed and documented for 1 of 1 microscopes used to perform dermatopathology microscopic examinations from 10/23/2024 to 01/15/2026. Findings include: 1. The laboratory's Microscope procedure stated, "Change bulbs as needed and have regular annual service and PM contracts performed." 2. On the day of survey, 01/15/2026 at 9:38 am, review of the laboratory's maintenance records revealed the laboratory failed to document annual preventative maintenance procedures performed from 10/23/2024 to 01/15/2026 for the following 1 of 1 microscope used to perform dermatopathology microscopic examinations: - Olympus BX40F4 3. The laboratory performed 350 dermatopathology microscopic examinations in 2025 (CMS 116, estimated annual volume, dated 01/14/2026). 4. The SDCD confirmed the above findings on 1/15/2026 at 11:35 am.

**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 review of laboratory policy, quality control (QC) logs, lack of documentation, and interview with the Senior Director of Clinical Development (SDCD), the laboratory failed to document a control slide of known reactivity to ensure acceptable staining characteristics of Hematoxylin & Eosin (H&E) stains for 1 of 18 days when dermatopathology microscopic slides were examined from 10/23

/2024 to 01/15/2026. Findings include: 1. The laboratory's Quality Assurance for Routine Stains procedure stated "A quality control slide will be run each day the lab operates. Each QC will be logged on the stain QC chart." 2. On the day of survey, 01/15/2026 at 10:09 am, a review of the laboratory's QC staining logs revealed the laboratory failed to document a control slide of known reactivity to ensure acceptable H&E staining characteristics for the following 1 of 18 days when dermatopathology microscopic slides were examined from 10/23/2024 to 01/15/2026: - 08/14/2025 3. Review of the laboratory's Mohs accession logs revealed that the laboratory performed 19 dermatopathology slide examinations on 08/14/2025. 4. The SDCD confirmed the above findings on 1/15/2026 at 11:35 am.

**D5781**

**CORRECTIVE ACTIONS**  
CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:  
Based on record review, lack of documentation, and interview with the Senior Director of Clinical Development (SDCD), the laboratory failed to document corrective action taken when room temperatures were recorded below the laboratory's acceptable range of 68 to 76 degrees Fahrenheit (F) for 5 of 15 days when dermatopathology microscopic examinations were performed from 10/23/2024 to 01/15/2026. Findings include: 1. On the day of survey, 01/15/2026 at 9:38 am, review of the laboratory's room temperature logs revealed room temperatures below the acceptable range of 68 to 76 F were recorded for the following when dermatopathology microscopic examinations were performed from 10/23/2024 to 01/15/2026: - 03/28/2025 (67.7 F) - 04/24/2025 (65.7 F) - 05/23/2025 (65.1 F) - 09/19/2025 (67 F) - 10/24/2025 (67.9 F) 2. The laboratory could not provide documentation of corrective actions taken when room temperatures were below the laboratory's established range. 3. Review of the laboratory's Mohs accession logs revealed that the laboratory performed a total of 111 dermatopathology slide examinations on the dates listed above. 4. The SDCD confirmed the above findings on 1/15/2026 at 11:35 am.

**D6076**

**LABORATORY DIRECTOR**  
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:  
Based on record review and interview with the Senior Director of Clinical Development (SDCD), the Laboratory Director (LD) failed to provide overall

management and direction of the laboratory in accordance with 493.1445 from 10/23/2024 to 01/15/2026. Refer to D6086 and D6093.

**D6086**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(3)(ii)

(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

This STANDARD is not met as evidenced by:  
Based on record review, lack of documentation, and interview with the Senior Director of Clinical Development (SDCD), the laboratory failed to ensure established procedures for the twice annual verification of accuracy for dermatopathology microscopic examination testing were followed for 2 of 2 peer review evaluations performed from 10/23/2024 to 01/15/2026. Findings include: 1. The laboratory's Proficiency Testing policy stated "Upon receipt of the pathology report from the Dermatopathologist, diagnosis of the slide specimen will be matched to the in-house diagnosis by the physician. Stain quality, visibility of epidermis, and next step required will also be compared against records." 2. On the day of survey, 01/15/2026 at 9:52 am, the laboratory failed to provide documentation for the review performed upon receipt of pathology reports from the Dermatopathologist for the following 2 of 2 peer review evaluations completed from 10/23/2024 to 01/15/2026: - Dermatology Partners - Semiannual Proficiency Testing Year: 2024 Testing Period: July 1 - December 31 - Dermatology Partners - Semiannual Proficiency Testing Year: 2025 Testing Period: January 1 - June 30 3. The SDCC confirmed the above findings on 1/15/2026 at 11:35 am.

**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 Senior Director of Clinical Development (SDCD), the laboratory director (LD) failed to ensure a Quality Assurance (QA) program was maintained and documented to ensure the quality of services provided for 14 of 14 months from 10/23/2024 to 01/15/2026. Findings include: 1. The Laboratory's Quality Assurance Procedure stated, "Monthly the nurse or Mohs histotech, along with the laboratory director or testing personnel, will check off the line items on the Monthly Quality Assurance Checklist." 2. On the date of the survey, 01/15/2026 at 9:56 am, the laboratory failed to provide monthly documentation for the QA evaluation performed to assess the laboratory's pre-analytical, analytical, and post-analytical processes for the following 14 of 14 months from 10/23/2024 to 01/15/2026: - November - December 2024 - January - December 2025 3. The SDCC confirmed the above findings on 1/15/2026 at 11:35 am. Repeat deficiency\*