

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2169802	(X3) Date Survey Completed 10/29/2025
Name of Provider or Supplier Ringpfeil Advanced Dermatology	Street Address, City, State 569 W Lancaster Ave, Haverford, 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
D0000	A recertification survey conducted by the Pennsylvania State Agency on 10/29/2025 found the Ringpfeil Advanced Dermatology Haverford laboratory to be out of compliance with the following condition: 493.1441 Condition: Laboratories performing high complexity testing; laboratory director.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of documentation and interview with Testing Personnel (TP) #2, the laboratory failed to establish and maintain a competency assessment procedure to assess the competency for 1 of 1 technical supervisor (TS), 1 of 1 clinical consultant (CC), and 1 of 1 general supervisor (GS) for their supervisory responsibilities performed in histopathology from 12/12/2023 to 10/29/2025. Findings include: 1. On the day of the survey, 10/29/2025 at 9:50 am, the laboratory failed to provide a competency assessment procedure to assess TS, CC and GS for their supervisory responsibilities. 2. The laboratory could not provide competency assessment records for the 1 of 1 CC (CMS 209 Personnel #2), 1 of 1 TS (CMS 209 Personnel #2) and 1 of 1 GS (CMS 209 Personnel #2) for their supervisory responsibilities performed from 12/12/2023 to 10/29/2025. 3. TP #2 confirmed the findings above on 10/29/2025 at 11:18 am. Repeat deficiency**</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(d) Reagents, solutions, culture media, control materials, calibration materials, and</p>

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 observation of the laboratory and interview with Testing Personnel (TP) #2, the laboratory failed to ensure that 4 of 6 reagents used to prepare microscopic dermatopathology slides were not used beyond the expiration dates from 12/12/2023 to date of survey. Findings include: 1. On the day of the survey 10/29/2025 at 8:45 am, observation during the laboratory tour revealed the following 4 of 6 expired reagents used to prepare microscopic dermatopathology slides from 12/12/2023 to 10/29/2025: - 1 opened set of Avantik tissue marker dye (Lot #156628, expired 8/31/2024). - 1 opened bottle of Sakura Tissue-Tek OCT Compound (expired 2/28/2025). - 1 opened bottle of Avantik Eosin-Y Cytoplasmic Stain (Lot #164413, expired 1/31/2025). - 1 opened bottle of Avantik Bluing Reagent (Lot #156132, expired 8/31/2025). 2. The laboratory performed an estimated 229 dermatopathology microscopic examinations in 2024 (CMS 116, dated 10/29/2025). 3. TP#2 confirmed the findings above on 10/29/2025 at 11:18 am.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on lack of maintenance records, and interview with Testing Personnel (TP) #2, the laboratory failed to assess the maintenance and function checks as defined by the manufacturer for 1 of 1 traceable thermometer/humidity monitor used to ensure acceptable operating temperatures were met in the dermatopathology laboratory from 05/26/2024 to 10/29/2025. Findings include: 1. The laboratory failed to provide documentation of maintenance and function checks for the following 1 of 1 traceable thermometer/humidity monitor used to monitor room temperature and humidity levels in the dermatopathology laboratory from 05/26/2024 to 10/29/2025: - Thomas Scientific traceable thermometer/humidity monitor (S/N 221547861, calibration expiration date 5/26/2024). 2. TP#2 confirmed the above findings on 10/29/2025 at 11:18 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 review of laboratory policy, lack of documentation, and interview with Testing Personnel (TP) #2, the Laboratory Director (LD) failed to provide overall management and direction in accordance with 493.1445 for 22 of 22 months from 12/12/2023 to 10/29/2025. Refer to D6093, D6103, D6106

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:

A. Based on review of the laboratory's Quality Assessment Program (QAP) Policy, lack of documentation, and interview with Testing Personnel (TP) #2, the Laboratory Director (LD) failed to ensure an established Quality Assessment (QA) program was maintained to ensure the quality of services provided by the laboratory for 22 of 22 months from 12/12/2023 to the date of survey. Findings include: 1. The laboratory's QAP stated, "Each of the laboratory's quality systems will undergo assessment on a regular basis to maintain and improve laboratory performance and services. This assessment includes the following practices: - All Quality Control (QC) logs for testing procedures, reagents, and equipment will be reviewed [by] the Laboratory Director or an appropriate designated staff member on a MONTHLY basis. - The Laboratory Director or an appropriate, designated staff member will conduct meetings with all relevant staff MONTHLY to communicate the results of corrective action, QC, and QA reviews and to address any concerns affecting laboratory performance. Additional staff meetings will be conducted to address any concerns or issues requiring more immediate attention." 2. On the date of survey, 10/29/2025 at 8:54 am, the laboratory failed to provide documentation of the LD's periodic QA evaluation performed to assess the laboratory's pre analytical, analytical, and post-analytical processes for 22 of 22 months from 12/12/2023 to 10/29/2025. 3. TP #2 confirmed the findings above on 10/29/2025 at 11:18 am. B. Based on review of the laboratory's Quality Assessment Program (QAP) Policy, lack of documentation and interview with Testing Personnel (TP) #2, the Laboratory Director (LD) failed to review and evaluate 3 of 3 "Quality assurance, proficiency testing" result reports annually to ensure maintenance of the accuracy, appropriateness, and confidentiality of histopathology examinations performed in 2024 and 2025. Findings include: 1. The laboratory's QAP stated, "The components of each [Proficiency] test performed will be reviewed by the Laboratory Director or an appropriate, designated staff member ANNUALLY to ensure maintenance of the accuracy, appropriateness, and confidentiality of testing." 2. On the day of survey, 10/29/2025 at 9:00 am, the laboratory failed to provide documentation for the annual review and evaluation of 3 of 3 "Quality assurance, proficiency testing" reports by the LD or designated staff member to ensure maintenance of the accuracy, appropriateness, and confidentiality of histopathology examinations performed in 2024 and 2025. 3. TP#2 confirmed the above findings on 10/29/2025 at 11:18 am.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(13)

(e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:
Based on review of the laboratory's Quality Assurance Program Policy, lack of documentation and interview with Testing Personnel (TP) #2, the Laboratory Director (LD) failed to ensure that procedures were established and followed to evaluate competency for 1 of 2 testing personnel (TP) who conducted preanalytical, analytical and postanalytical phases of testing in dermatopathology from 12/12/2023 to 10/29/2025. Findings include: 1. The laboratory's Quality Assurance policy stated, "This laboratory will ensure that all testing personnel are properly trained and are competent prior to testing patient specimens. Starting 6 months after hire date and then ANNUALLY thereafter, the laboratory director and/or technical consultant will review the performance of each employee working in the laboratory to assure employee competency." 2. On the day of the survey, 10/29/2025 at 9:50 am, the laboratory failed to provide documentation of the annual competency assessment for TP #1 (CMS 209 Personnel #2) in 2024. 3. TP #2 confirmed the findings above on 10/29/2025 at 11:18 am.

D6106

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(14)

(e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and

This STANDARD is not met as evidenced by:
Based on review of the laboratory's procedure manual and interview with testing personnel (TP) #2, the laboratory director (LD) failed to ensure that 27 of 27 procedures available to personnel that performed testing were approved before use from 12/12/2023 through the day of survey. Findings include: 1. The laboratory's Quality Assessment Procedures policy stated, "New procedures and all changes to the Manual will be approved, signed and dated by the Laboratory Director before use." 2. On the day of the survey, 10/29/2025 at 9:09 am, review of the laboratory's current procedure manual revealed the LD failed to approve the following 27 of 27 procedures used by personnel in the laboratory from 12/12/2023 to 10/29/2025: - Quality Control Policies and Documentation - Quality Assurance Program - Test Procedures - Reagents - Laboratory Daily Maintenance - Processing Tissue - Frozen Section Procedure - Hematoxylin and Eosin Stain - Slide Labeling - Coverslipping - Storage of Diagnosed Slides - Cryostat Maintenance - Disinfecting cryostat after known positive HIV case - Stain maintenance - Specimen Acceptance or Rejection - Corrective Action - Bloodborne Pathogen Exposure Control Plan - Hazardous Chemical Communication Plan - Chemical Hygiene Plan - Personal Protective/Safety Equipment - Quality Assessment General Policy - Procedure Manual - Facilities - Test Methods - Temperature Logs and Graphs - Labeling - Equipment Maintenance - Confidentiality of Patient Information 3. TP#2 confirmed the findings on 10/29/2025 at 11:18 am.