

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D0692882	<b>(X3) Date Survey Completed</b>  09/09/2025
<b>Name of Provider or Supplier</b>  Advanced Dermatology Of Pennsylvania	<b>Street Address, City, State</b>  350 3rd Street, Beaver, 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>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation, and interview with the Histotechnologist (HT), the laboratory failed to monitor and document room temperature and humidity to ensure operating conditions were met for 2 of 2 microscopes used to perform Potassium Hydroxide (KOH) microscopic slide examinations from 10/18/2023 to 09/09/2025. Findings Include: 1. On the day of survey, 09/09/2025 at 11:32 am., the laboratory failed to provide documentation for monitoring room temperature (laboratory's acceptable range 5 - 35 degrees Celsius) and relative humidity (laboratory's acceptable range 0 - 60%) to ensure operating conditions were met for the following instrumentation used to perform KOH microscopic slide examinations from 10/18/2023 to 09/09/2025: - 1 of 1 Leica ATC 2000 microscope (s/n 9419376) - 1 of 1 Olympus CH microscope (s/n 490354) 2. The CMS 116 form submitted at the time of the survey revealed that 5 KOH Prep examinations were performed in 2024. 3. The HT confirmed the findings above on 09/09/2025 at 12:04 pm.</p>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p>

(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 observation of the laboratory and interview with the Histotechnologist (HT), the laboratory failed to ensure that 1 of 1 reagent used to perform Potassium Hydroxide (KOH) microscopic slide examinations was not used beyond its expiration date from 03/31/2022 to date of survey. Findings include: 1. On the day of the survey 09/09/2025 at 11:32 am, observation during the laboratory tour revealed the following 1 of 1 expired reagent used to perform KOH microscopic slide examinations from 03/31/2022 to 07/29/2025: - 1 opened bottle of EDM3 Solutions KOH 20% in DMSO (Lot #0091 expired 03/31/2022). 2. The CMS 116 form submitted at the time of the survey revealed that 5 KOH Prep examinations were performed in 2024 3. The HT confirmed the findings above on 09/09/2025 at 12:04 pm.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)

(b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to--

This STANDARD is not met as evidenced by:

Based on lack of documentation, and interview with the Histotechnologist (HT), the Technical Consultant (TC) failed to assess the annual competency of 1 of 4 testing personnel (TP) that performed Potassium Hydroxide (KOH) microscopic slide examinations in 2024. Findings Include: 1. On the day of the survey, 09/09/2025 at 9:26 am, the laboratory could not provide documentation of annual competency assessment performed on TP#4 (CMS personnel form) for KOH Prep testing performed from 10/18/2023 to 09/09/2025. 2. The CMS 116 form submitted at the time of the survey revealed that 5 KOH Prep examinations were performed in 2024 3. The HT confirmed the findings above on 09/09/2025 at 12:04 pm.

**D6047**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)(i)

(b)(8)(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;

This STANDARD is not met as evidenced by:

Based on record review, and interview with the Histotechnologist (HT), the Technical Consultant (TC) failed to assess the annual competency of 1 of 4 testing personnel (TP) that performed Potassium Hydroxide (KOH) microscopic slide examinations in 2024 through direct observation of routine patient test performance. Findings Include: 1. On the day of the survey, 09/09/2025 at 9:26 am, the laboratory could not provide documentation of direct observation of routine patient test performance, performed on TP #5 (CMS personnel form) for KOH Prep testing performed from 10/18/2023 to 09/09/2025. 2. The CMS 116 form submitted at the time of the survey revealed that 5

	<p>KOH Prep examinations were performed in 2024 3. The HT confirmed the findings above on 09/09/2025 at 12:04 pm.</p>
<b>D6048</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)(ii)</p> <p>(b)(8)(ii) Monitoring the recording and reporting of test results;</p> <p>This STANDARD is not met as evidenced by: Based on record review, and interview with the Histotechnologist (HT), the Technical Consultant (TC) failed to assess the annual competency of 1 of 4 testing personnel (TP) that performed Potassium Hydroxide (KOH) microscopic slide examinations in 2024 through monitoring the recording and reporting of test results. Findings Include: 1. On the day of the survey, 09/09/2025 at 9:26 am, the laboratory could not provide documentation of monitoring the recording and reporting of test results, performed on TP #5 (CMS personnel form) for KOH Prep testing performed from 10/18/2023 to 09/09/2025. 2. The CMS 116 form submitted at the time of the survey revealed that 5 KOH Prep examinations were performed in 2024 3. The HT confirmed the findings above on 09/09/2025 at 12:04 pm.</p>
<b>D6049</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)(iii)</p> <p>(b)(8)(iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;</p> <p>This STANDARD is not met as evidenced by: Based on record review, and interview with the Histotechnologist (HT), the Technical Consultant (TC) failed to assess the annual competency of 1 of 4 testing personnel (TP) that performed Potassium Hydroxide (KOH) microscopic slide examinations in 2024 through review of intermediate test results or worksheets, quality control records, proficiency testing results and preventive maintenance records. Findings Include: 1. On the day of the survey, 09/09/2025 at 9:26 am, the laboratory could not provide documentation of review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records, performed on TP #5 (CMS personnel form) for KOH Prep testing performed from 10/18/2023 to 09/09/2025. 2. The CMS 116 form submitted at the time of the survey revealed that 5 KOH Prep examinations were performed in 2024 3. The HT confirmed the findings above on 09/09/2025 at 12:04 pm.</p>