

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 39D2220431	<b>(X3) Date Survey Completed</b> 07/29/2025
<b>Name of Provider or Supplier</b> Pa Dermatology Partners - King Of Prussia	<b>Street Address, City, State</b> 200 Mall Blvd, King Of Prussia, 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 conducted by the Pennsylvania State Agency on 07/29/2025 found the PA Dermatology Partners - King of Prussia laboratory to be out of compliance with the following condition: 493.1441 Condition: Laboratories performing high complexity testing; laboratory director.
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <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.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory and interview with the Director of Clinical Development (DCD), the laboratory failed to ensure that 3 of 7 tissue marking reagents used for macroscopic histopathology examinations (grossing and inking) were not used beyond their expiration date from 02/28/2025 to date of survey. Findings include: 1) On the day of survey 07/29/2025 at 12:48 pm while touring the laboratory, the surveyor discovered the following 3 of 7 expired tissue marking reagents used for the grossing and inking of histopathology specimens from 02/28/2025 to 07/29/2025: - 1 opened bottle of Avantik Orange Tissue Marking Dye (expired 02/28/2025) - 1 opened bottle of Avantik Green Tissue Marking Dye (expired 04/30/2025) - 1 opened bottle of Avantik Yellow Tissue Marking Dye (expired 06/30/2025) 2. The DCD confirmed the findings above on 07/29/2025 at 1:00 pm.</p>
<b>D5805</b>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>(c) The test report must indicate the following: (c)(1) For positive patient</p>

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 Director of Clinical Development (DCD), the laboratory failed to include the address of the location where Mohs microscopic slide examinations were performed on 2 of 2 patient test reports reviewed from 08/22/2023 to the day of survey. Findings Include: 1. On the day of survey, 07/29/2025 at 12:40 pm, review of 2 of 2 patient test reports (Mohs maps) revealed the laboratory failed to ensure the addition of the address of the laboratory where Mohs microscopic slides were examined from 08/22/2023 to 07/29/2025. 2. The laboratory reported an estimated annual volume of 800 histopathology examinations performed in 2024 (CMS 116, dated 07/28/2025). 3. The DCD confirmed the findings above on 07/29/2025 at 1:00 pm.

**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 the Director of Clinical Development (DCD), the Laboratory Director failed to provide overall management and direction in accordance with 493.1445 for 18 of 23 months from 08/22/2023 to 07/29/2025. Refer to D6093

**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 review of the laboratory's Quality Assurance (QA) policy, lack of documentation, and interview with the Director of Clinical Development (DCD), the Laboratory Director (LD) failed to ensure an established QA program was maintained to ensure the quality of services provided by the laboratory for 18 of 23 months from 08/22/2023 to the date of survey. Findings include: 1. The laboratory's Quality Assurance policy states, "On months when patient testing is being performed in the laboratory, the nurse or Mohs histotechnician, along with the laboratory director, will check off the line items on the Monthly Quality Checklist. The laboratory director will then be responsible for signing off on completed quality assurance checklists." 2. On

the date of survey, 07/29/2025 at 12:46 pm the laboratory failed to provide documentation of the monthly quality checklist used to perform periodic QA evaluation and assess the laboratory's pre-analytical, analytical, and post-analytical processes for the following 18 of 23 months from 08/22/2023 to 07/29/2025: - January 2024 through December 2024 - January 2025 through June 2025 3. The laboratory performed 800 histopathology examinations in 2024 (CMS 116, estimated annual volume, dated 07/28/2025). 4. The DCD confirmed the findings above on 07/29/2025 at 1:00 pm. \*REPEAT DEFICIENCY