

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2290721	(X3) Date Survey Completed 10/28/2025
Name of Provider or Supplier Dermatology Partners - Yardley	Street Address, City, State 209 Floral Vale Blvd, Yardley, 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 10/28/2025 found the Dermatology Partners Yardley laboratory to be out of compliance with the following condition: 493.1290 Condition: Postanalytic Systems.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the laboratory's peer review records, and interview with the Senior Director of Clinical Development (SDCD), the laboratory failed to ensure that the verification of accuracy for microscopic examinations for histopathology was performed at least twice annually, as required for tests not included in subpart I for 1 of 1 year in 2024. Findings Include: 1. On the day of the survey, 10/28/2025 at 09:35 am, review of the laboratory's peer review records revealed the laboratory failed to ensure the verification of accuracy for histopathology slide examinations was performed at least twice annually for 1 of 1 year in 2024. 2. The laboratory performed 15,000 microscopic slide examinations(histopathology) in 2024 (CMS-116, estimated annual volume, dated 10/28/2025). 3. The SDCCD confirmed the findings above on 10/28/2025 at 09:40 am.</p>
D5413	<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</p>

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 lack of documentation and interview with the Senior Director of Clinical Development (SDCD), the laboratory failed to monitor and document room temperature and humidity to ensure operating conditions were met for 1 of 1 Olympus BX45 microscope used to perform histopathology microscopic slide examinations from 02/28/2024 to 10/28/2025. Findings include: 1. The manufacturers operating environment specifications stated the following: -Olympus BX45 microscope: 5-40 degrees Celsius (ambient temperature); maximum 80 % relative humidity 2. On the day of the survey, 10/28/2025, the laboratory failed to provide documentation for the monitoring of room humidity to ensure operating conditions were met for the following instruments used to perform histopathology microscopic examinations from 02/28/205 to 10/28/2025: - 1 of 1 Olympus BX45 microscope 3. The laboratory performed 15,000 histopathology slide examinations in 2024 (CMS 116, estimated annual volume, dated 010/28/2025). 4. The SDCD confirmed the above findings on 10 /28/2025 at 09:30am.

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:

A. Based on review of quality control (QC) records, lack of documentation and interview with the Senior Director of Clinical Development (SDCD), the laboratory failed to document positive and negative stain reactivity each time of use for 24 of 24 immunohistochemical stains (IHC) used for histopathology slide examinations from 02 /11/2025 to 10/28/2025. Findings include: 1. On the day of survey 10/28/2025 at 09: 40 am, the laboratory failed to provide documentation for positive and negative reactivity at each time of use for the following 24 of 24 immunohistochemical stains (IHC) used for microscopic histopathology examinations performed from 02/11/2025 to 10/28/2025: SOX10 MART CD3 CD4 CD8 CD20 CD30 CD31 CD34 CD68 CD117 CEA CK7 CK20 Desmin EMA Ep-Cam Factor XIIIa HMB-45 Ki67 Pan-Keratin Prame S100 SMA 2. The laboratory performed 31 cases for IHC staining in 2025. 3. The laboratory performed 15,000 histopathology slide examinations in 2024 (CMS 116, estimated annual volume, dated 010/28/2025). 4. The SCCD confirmed the findings above on 10/28/2025 at 9:40 am. B Based on review of quality control (QC) records, lack of documentation and interview with the Senior Director of Clinical Development (SDCD), the laboratory failed to document a control slide of known reactivity for 6 of 6 differential or special stains used for microscopic histopathology slide examinations from 02/11/2025 to 10/28/2025. Findings include: 1. On the day of survey 10/28/2025 at 09:40 am, the laboratory failed to provide documentation a control slide of know reactivity for the following 6 of 6 special stains

	<p>were used for microscopic histopathology examinations performed from 02/11/2025 to 10/28/2025: Alican Blue Acid Fast Bacteria (AFB) Fite Gram Iron Hematoxylin and Eosin stain (H&E) 2. The laboratory performed 15,000 histopathology slide examinations in 2024 (CMS 116, estimated annual volume, dated 010/28/2025). 3. The SCCD confirmed the findings above on 10/28/2025 at 9:40 am.</p>
<p>D5800</p>	<p>POSTANALYTIC SYSTEMS CFR(s): 493.1290</p> <p>Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in 493.1299 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of patient test reports and interview with the Senior Director of Clinical Development (SDCD), the laboratory failed to meet applicable postanalytical systems requirements in 493.1291 for 1 of 2 microscopic slide examinations (histopathology) patient test reports reviewed from 02/28/2024 to the date of the survey. (refer to D5805).</p>
<p>D5805</p>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with the Senior Director of Clinical Development (SDCD), the laboratory failed to include the address of the location where microscopic slide examinations (histopathology) were performed on 1 of 2 patient test reports reviewed from 02/28/2024 to the date of the survey. Findings include: 1. On the day of survey, 10/28/2025 at 9:45 am, review of 1 of 2 patient test reports revealed the laboratory failed to ensure the addition of the address of the laboratory where microscopic slides were examined from 02/28/2024 until 10/28/2025. 2. The laboratory performed 15,000 microscopic slide examinations (histopathology) in 2024 (CMS 116, estimated annual volume, dated 10/28/2025). 3. The SDCC confirmed the above findings on 10/28/2025 at 09:45 am. . *** This is a repeat deficiency previously cited on February 28, 2024.</p>