Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2238875	11/04/2025
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Partners-Port Richmond	2310 E Allegheny Ave, Philadelphia, 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 11/04/2025 found the Dermatology Partners Port Richmond laboratory to be out of compliance with the following condition: 493.1219 Condition: Histopathology.
D5028	HISTOPATHOLOGY CFR(s): 493.1219 If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1273, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: 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 meet applicable histopathology requirements in 493.1256(e)(3), for documentation of positive and negative stain reactivity each time of use for 30 of 30 immunohistochemical stains (IHC) used for histopathology slide examinations from 12 /21/2023 to 11/04/2025. Refer to D5601.
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 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 BX46 microscope used to perform histopathology microscopic slide examinations from 12/21/2023 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, 11/04/2025, the laboratory failed to provide documentation for the monitoring of room temperature and humidity to ensure operating conditions were met for the following instruments used to perform histopathology (Mohs) microscopic examinations from 12/21/23 to 10/28/2025: - 1 of 1 Olympus BX46 microscope 3. The laboratory performed 18,000 histopathology slide examinations in 2024 (CMS 116, estimated annual volume, dated 011/04/2025). 4. The SDCD confirmed the above findings on 11/04/2025 at 01:30 pm.
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 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 30 of 30 immunohistochemical stains (IHC) used for microscopic histopathology slide examinations from 12/21/2023 to 11/04/2025. Findings include: 1. On the day of survey, 11/04/2025 at 12:40 pm, the laboratory failed to provide documentation for positive and negative reactivity at each time of use for the following 30 of 30 IHC used for microscopic histopathology examinations performed from 12/21/2023 to 11 /04/2025: SOX10 BCL-2 CD3 Treponema Pallidum Antibody CD163 p-63 CD20 Cam5.2 CD138 Actin Muscle Specific CD31 HHV8 CD34 CD 1a CD68 Mycobacteral CD117 CEA CK7 CK20 Desmin Melan A Grocott's Methenamine Factor XIIIa Ber-EP4 Ki67 Pan-Keratin Prame S100 SMA 2. The laboratory performed 1249 cases for IHC staining in 2025. 3. The SCCD confirmed the findings above on 11/04/2025 at 12:40 pm. *** This is a repeat deficiency previously cited on December 21, 2023.
D5805	TEST REPORT CFR(s): 493.1291(c) (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. 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 12/21/2023 to the date of the survey. Findings include: 1. On the day of survey, 11/04/2025 at 1:00 pm, review of 1 of 2 patient test reports (Mohs maps) revealed the laboratory failed to ensure the addition of the address of the laboratory where microscopic slides were examined from 12/21/2024 until 10/28/2025. 2. The laboratory performed 18,000 microscopic slide examinations (histopathology) in 2024 (CMS 116, estimated annual volume, dated 11/04/2025). 3. The SDCD confirmed the above findings on 11/04/2025 at 01:15 pm
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 Senior Director of Clinical Development (SDCD), the Laboratory Director (LD) failed to ensure an established QA program was maintained to ensure the quality of services provided by the laboratory for 16 of 23 months from 12/21/2023 to 11/04/2025. Findings include: 1. The laboratory's Quality Assurance policy stated, "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 the survey, 11/04/2025 at 1:00 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 16 of 23 months from 12/21/2023 to 11/04/2025: - January to December 2024 - January to April 2025 3. The laboratory performed 18,000 histopathology slide examinations in 2024 (CMS 116, estimated annual volume, dated 011/04/2025). 4. The SDCD confirmed the findings above on 11/04/2025 at 1:15 pm.