Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0195567	10/30/2025
Name of Provider or Supplier	**Street Address, City, State**	
Pennsylvania Dermatology Partners - Bensalem	1950 Street Road, Suite 100, Bensalem, 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 10/30/2025 found the Pennsylvania Dermatology Partners Bensalem laboratory to be out of compliance with the following condition: 493.1250 Condition: Analytic systems.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of temperature logs, lack of documentation, and interview with the Laboratory Director, the laboratory failed to meet applicable analytic systems requirements as required under 493.1282, when refrigerator storage temperatures were below the laboratory's acceptable range for Immunohistochemical (IHC) stains used when histopathology microscopic examinations were performed for 15 of 34 days from 10/01/2024 to 10/30/2025. Refer to D5781
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)

	(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's temperature logs, lack of documentation, and interview with the Laboratory Director (LD), the laboratory failed to document corrective action taken when refrigerator storage temperatures were recorded below the laboratory's acceptable range of 35.6 to 46.4 degrees Fahrenheit for Immunohistochemical (IHC) stains used when histopathology microscopic examinations were performed for 15 of 34 days from 10/01/2024 to 10/30/2025. Findings include: 1. On the day of survey 10/30/25 at 11:04 am, review of the laboratory's refrigerator temperature logs revealed IHC stain (MART-1) storage temperatures below 35.6 to 46.4 degrees Fahrenheit were recorded for the following days from 10/01/2024 to 10/30/2025: - 10/14/24 - 10/22/24 - 10/28/24 - 11/11/24 - 2 /25/25 - 4/22/25 - 5/5/25 - 5/6/25 - 5/19/25 - 7/15/25 - 7/22/25 - 9/2/25 - 10/1/25 2. The laboratory could not provide documentation of corrective actions taken when refrigerator temperatures were recorded out of the laboratory's acceptable range. 3. Review of the laboratory's test logs revealed that the laboratory performed 53 histopathology slide examinations using IHC stains (MART-1) from 10/01/2024 to 10 /30/2025. 4. The LD confirmed the above findings on 10/30/2025 at 11:35 am. *REPEAT DEFICIENCY*