Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2017413	05/12/2025
Name of Provider or Supplier	**Street Address, City, State**	
Upmc Smh Dermatology	2585 Freeport Rd, Pittsburgh, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Histotechnologist (HT), the laboratory failed to ensure that the verification of accuracy for MOHS microscopic examinations were performed at least twice annually, as required for 1 of 1 test not included in subpart I from 05/12/2023 to the date of the survey. Findings include: 1. On the day of survey, 05/12/2025 at 01:30 pm, the laboratory failed to provide documentation for the verification of accuracy performed for MOHS microscopic examinations at least twice annually from 05/13/2023 to 05/12/2025. 2. The laboratory failed to provide a policy for verification of accuracy for MOHS microscopic examinations. 3. The laboratory reported an annual volume of 924 microscopic examinations/tests performed in Histopathology (CMS 116 estimated annual volumen for 2024). 4. The HT confirmed the above findings on 05/13/2025 at 01:30 pm.
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 review of laboratory records, 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 Olympus BX46 Microscopes used to perform histopathology slide examinations from 02/01 /2025 to the date of survey. Findings include: 1. The operating environment listed in the instruction manual for the Olympus biological microscope states: "microscope should be kept at temperatures between 5C-40C/41F-104F, with a maximum humidity of 80%." 2. On the date of the survey, 05/12/2025 at 01:30 pm, the laboratory failed to provide documentation for monitoring room temperatures and humidity to ensure operating conditions were met for 2 of 2 Olympus BX46 microscopes used to perform histopathology slide examinations from 02/01/2025 to 05/12/2025. 3. The laboratory performed 924 (CMS-116 estimated annual volume) histopathology slide examinations in 2024. 4. The HT confirmed the findings above on 05/12/2025 at 01: 30 pm.