Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0696343	01/30/2023
Name of Provider or Supplier	**Street Address, City, State**	
Jefferson Dermatology Associates	33 S 9th Street, Suite 740, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the competency assessment records and interview with the histotechnician (HT), the laboratory failed to establish written policies and procedures to assess the competency of 1 of 2 clinical consultants (CC) for their supervisory responsibilities from 12/21/2020 to the date of the survey. Findings Include: 1. On the day of the survey, 01/30/2023 at 09:50 am, the laboratory could not provide a written procedure to assess the competency of 1 of 2 CC (CMS 209 CC# 2) for their supervisory responsibilities from 12/21/2020 to 01/30/2023. 2. The laboratory could not provide competency assessment records for 1 of 2 CC (CMS 209 CC #2) for their supervisory responsibilities in 2021 and 2022. 3. The HT confirmed the findings above on 01/30/2023 around 11:30 am.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 the laboratory's temperature records, lack of documentation, and interview with the histotechnician (HT), the laboratory failed to record the relative humidity and internal cryostat temperature to ensure operating conditions were met for 1 of 1 Advanitk QS11 Cryostats from October 2021 to the date of the survey. Findings Include: 1. On the day of the survey, 01/30/2023 at 10:06 am, the laboratory failed to provide documentation for the relative humidity and internal cryostat temperature of 1 of 1 Advantik QS11 Cryostats to ensure operating conditions were met from October 2021 to January 2023. 2. The TJUS Mohs Dermatology Lab Policy and Procedure Manual: Center City states, "Temperature and humidity is checked and recorded at the beginning of the surgical day, before any procedures." 3. The laboratory performed 1487 MOHS micrographic surgery slide examinations in 2022 (CMS 116 annual volume). 4. The HT confirmed the findings above on 01/30/2023 around 11:30 am.
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. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control (QC) staining records and interview with the histotechnician (HT), the laboratory failed to document negative and positive staining reactivity each time of use for 1 of 1 immunohistochemical (IHC) stains used for MOHS micrographic surgery (MOHS) slide examinations from 12/20/2020 to the date of the survey. Findings include: 1. On the day of the survey, 01/30/2023 at 10:20 am, review of the laboratory's stain QC log revealed that a control for negative and positive reactivity was not documented each time of use for 1 of 1 IHC stains (Mart-1) used for MOHS slide examinations from 12/20/2020 to 01/30/2023. 2. The HT confirmed the finding above on 01/30/2023 at 11:30 am.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the laboratory competency assessment records and interview with the histotechnician (HT), the technical supervisor (TS) failed to evaluate the annual competency assessment for 1 of 2 testing personnel (TP) who performed MOHS

	micrographic surgery slides examinations from 12/21/2020 to the day of the survey. Findings include: 1. On the day of survey, 01/30/2023 at 09:50 am, the laboratory could not provide competency assessment records for 1 of 2 TP (CMS 209 TP #2) who performed MOHS micrographic surgery slide examinations from 12/21/2020 to 01/30/2023. 2. The laboratory performed 1487 MOHS micrographic surgery slide examinations in 2022 (CMS 116 annual volume). 3. The HT confirmed the finding above on 01/30/2023 around 11:30 am.