Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	41D1097479	09/11/2023
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Professionals, Ap	1672 South County Trail Suite 101, East Greenwich, RI	

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 record review and interview with Histotechnician 1 (HT1), the laboratory failed to establish written procedures for testing personnel competency assessment for Potassium Hydroxide (KOH) and Scabies testing. Findings include: 1. Record review on 08/21/2023 of the laboratory's "Skin Scraping for Potassium Hydroxide, Tzanck Smear, Scabies Prep Procedure Manual" signed by the laboratory director on 05/11 /2019 revealed there was no procedure for competency assessment of testing personnel who perform KOH and Scabies testing. 2. Interview on 08/21/2023 with HT1 at 12:30 PM revealed, "The procedure manuals are not up to date. This might be an old manual. Someone else is now in charge of KOH and Scabies testing. They might have an updated manual with a competency policy but the person in charge is on vacation. I will send it to you when they get back." 3. Record review on 08/21 /2023 of the laboratory's competency records revealed a lack of documentation for competency assessment of KOH and Scabies for 10 of 10 testing personnel for 2021 and 2022. 4. Record review on 09/01/2023 of an email from the laboratory received on 08/31/2023 at 3:49 PM containing the updated KOH and Scabies procedures revealed there was no procedure for competency assessment of testing personnel who perform KOH and Scabies testing. 5. The laboratory performs 62 tests in the specialty of Microbiology annually.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a)

	A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: A. Based on record review and interview with Histotechnician 1 (HT1), the laboratory failed to follow the approved "Mohs Lab Quality Assurance Policy" procedure for 1 out of 3 peer review cases for competency evaluation of Testing Personnel 1 (TP1) in December 2022. Findings include: 1. Record review on 08/21/2023 of the laboratory's Mohs competency records for TP1 dated 12/06/2022 revealed HT1 failed to send all of the slides for 1 out of 3 Mohs cases sent for peer review. 2. Record review on 08/21/2023 of the laboratory's "Mohs Lab Quality Assurance Policy" procedure revealed: "Three Mohs cases will be chosen randomly once every six months from the total number of Mohs surgical cases performed within those six months. The slides are sent to one of our Mohs surgeon/dermatopathologist in another location." 3. Interview with HT1 on 08/21/2023 at 12:30 PM confirmed the findings above. HT1 stated, "I forgot to send all the slides." B. Based on record review and interview with Histotechnician 1 (HT1), the laboratory failed to follow their approved "Equipment Quality Control for Cryostats" procedure for 2 of 2 cryostats in 2022. Findings include: 1. Record review on 08/21/2023 of the laboratory's "Equipment Quality Control for Cryostats" procedure revealed: a. "Manual defrost of machine is done every six months and documented." b. "The air grill on the cryostat is cleaned as part of the maintenance every six months." 2. Record review on 08/21/2023 of the laboratory's 2022 "Maintenance Record for Mohs Lab" form revealed the laboratory performed the required maintenance referenced in 2a and 2b above only one time in 2022 for 2 of 2 cryostats. 3. Interview with HT1 on 08/21/2023 at 12:30 PM confirmed the maintenance procedure was not followed. HT1 stated, "I missed the second cryostat maintenance in 2022." C. Based on record review, surveyor observation, and interview with Histotechnician 1 (HT1), the laboratory failed to follow their approved "Specimen Handling, Storage, Transport, Preservation and Identification" procedure for 2 of 8 Mohs cases. Findings include: 1. Record review on 08/21/2023 of the documentation and slides of 8 Mohs cases revealed: a. The slides were relabeled with a secondary white sticker label. b. The accession number on the secondary label did not match the Mohs map and final patient test report for 2 of 8 Mohs cases. 2. During surveyor observation on 08/21/2023 at 12:30 PM, HT1 peeled back the secondary labels on the 2 mislabeled slides noted in C1b above to reveal the correct accession numbers were written on the physical slides under the label. 3. Record review on 09/11/2023 of an email received from the laboratory on 09/11/2023 at 12:44 PM containing the "Specimen Handling, Storage, Transport, Preservation and Identification" procedure section 3.4.10 revealed, "Slides are labeled with unique case number, patient last name, stage (designated with Roman numerals [I,, II, III, ...]), and piece number (designated with Arabic numeral [1,2,3])." 4. During staff interview with HT1 on 08/21/2023 at 12:30 PM, HT1 confirmed the slides in C1b above were mislabeled and stated, "I know the procedure doesn't say it but I relabel the slides so they look nicer."
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use

	and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on record review and staff interview with Histotechnician 1 (HT1), the laboratory failed to remove discontinued procedures from the procedure manual. Findings include: 1. Record review on 8/21/2023 of the laboratory's "Mohs Micrographic Surgery Laboratory Manual" signed by the laboratory director (LD) on 8 /15/2023 revealed: a. The "Laboratory Protocols and Quality Control Program" contained a section titled "Fume Hood Maintenance." The laboratory does not have a fume hood. b. Section 6 "Staining H&E of Frozen Sections" contained 3 different staining protocols. Two of the 3 staining protocols are no longer in use. c. Section 13 "Proficiency Testing" procedure is no longer in use. d. The above discontinued procedures were not removed from the manual and dated with a date of discontinuance. 2. Record review on 8/21/2023 of the laboratory's "Skin Scraping for Potassium Hydroxide, Tzanck Smear, Scabies Prep Procedure Manual" revealed procedure section 2 contained a protocol for the discontinued Tzanck Smear test. 3. Staff interview with HT1 on 8/21/2023 at 12:00 PM confirmed the above findings. HT1 stated: a. "We don't have a fume hood anymore." b. "The staining protocol that is currently in use is the one that matches the protocol posted on the wall in the laboratory." c. "We have a new procedure for Mohs proficiency testing." d. "We no longer perform Tzanck testing." e. "The procedure manuals are not up to date. The "Skin Scraping for Potassium Hydroxide, Tzanck Smear, Scabies Prep Procedure Manual" might be an old manual. Someone else is now in charge of KOH and Scabies testing. They might have an updated manual but the person in charge is on vacation. I will send it to you when they get back. I wasn't sure what to throw away so I just kept everything including this manual."
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 record review and staff interview with Histotechnician 1 (HT1), the laboratory failed to define acceptable ranges for room temperature and humidity to ensure the proper function of 2 of 2 cryostats. Findings include: 1. Record review on 08/21/2023 of the laboratory's "Daily log for room temperature, cryostat temperature, lab cleaned" logs from October 2021 through August 21, 2023 revealed the log did not contain acceptable ranges for room temperature, humidity, and cryostat temperature. 2. Record review on 08/21/2023 of the laboratory's "Mohs Micrographic Surgery Laboratory Manual" signed by the laboratory director (LD) on 8/15/2023 revealed the manual did not contain acceptable ranges for room temperature and humidity. 3. Staff interview with HT1 and the LD on 8/21/2023 at 12:00 PM confirmed the above findings.

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 record review and interview with Histotechnician (HT1), the laboratory failed to document corrective action when room temperature was out of the manufacturer's required range for 2 of 2 Leica Cryostats. Findings include: 1. Record review on 08/21/2023 of the laboratory's "Daily log for room temperature, cryostat temperature, lab cleaned" logs for Cryostat 1 and 2 from October 1, 2021 through August 21, 2023 revealed: a. The logs did not contain the acceptable range for room temperature for the use of the Leica Cryostats. b. The room temperature was out of the manufacturer's required range for Cryostat 1 and 2 for 349 of 351 days they were used for patient testing. 2. Record review on 8/21/2023 of the Leica CM1510 Cryostat Instruction Manual, Section 6.1 Site Requirements revealed, "Room temperature always below 22 degrees Celsius." 3. Record review on 8/21/2023 of the Laboratory Protocols and Quality Control Program manual, section 7.0 Cryostat Maintenance revealed: a. "Temperature range is -20 C to -30 C." b. "Corrective action is taken and documented if temperature exceeds range." 4. Interview with HT1 on 8/21/2023 at 12:30 PM confirmed the laboratory failed to document corrective action when the room temperature was out of manufacturer's required range and continued with use of the Leica Cryostats on those days. HT1 stated, "I just write the temperature down." 5. The laboratory performs 2,000 tests annually in the subspecialty of Histopathology.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on record review, surveyor observation, and staff interview with Histotechnician 1 (HT1), the laboratory director failed to ensure that testing systems used by personnel in the laboratory provide quality laboratory services in all aspects

	of test performance. Findings include: 1. Record review on 08/21/2023 of the "Skin Scraping for Potassium Hydroxide, Tzanck Smear, Scabies Prep Procedure Manual" signed by the laboratory director on 05/11/2019 revealed there was no procedure for competency assessment of testing personnel who perform KOH and Scabies testing. Refer to 5209. 2. Record review on 08/21/2023 of the laboratory's "Mohs Micrographic Surgery Laboratory Manual" procedure manual revealed: a. Three procedures were not followed correctly by the laboratory. Refer to 5401. b. The procedure manual contained procedures that were no longer being performed by the laboratory. Refer to 5409. c. The laboratory did not have established ranges for room temperature or humidity. Refer to 5413. d. The laboratory did not take corrective action when temperatures were out of range. Refer to 5781. 3. Interview with HT1 on 08/21/2023 at 12:30 PM confirmed the above findings.