Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0865928	08/24/2023
Name of Provider or Supplier	**Street Address, City, State**	
Highlands Dermatology And Surgical Associates	112 North Walnut, Cookeville, TN	

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	During a recertification survey that was completed on 8/24/23, the laboratory was found out of compliance with the following conditions: 42 CFR 493.1487, Laboratories performing high complexity testing; testing personnel
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: Based on review of the laboratory's procedure manual and staff interview, the laboratory failed to follow its' own written policy for reviewing the procedure manual annually in 2021, 2022, and 2023. The findings include: 1. Review of the laboratory's procedure manual under the section titled, "Review Policy" revealed the following statement: "This procedure Manual is reviewed by the Laboratory Director annually and at other times as required by major changes in procedure or other circumstances affecting laboratory performance of the test". 2. Review of the procedure manual under the section titled, "Review by Laboratory Director" revealed no documented laboratory director signature for 2021, 2022, and 2023. 3. Interview with the office manager and lead histotechnician on 8/24/23 at 1:30 p.m. confirmed the laboratory failed to follow its' own written policy for reviewing the procedure manual annually in 2021, 2022, and 2023.
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 observation of the laboratory, review of the manufacturer's operating manuals, lack of records, and staff interview, the laboratory failed to document ambient temperature and humidity for the area the Avantik QS12 and QS11 cryostats were used for tissue processing in 2021, 2022, and 2023. The findings include: 1. Observation of the laboratory on 8/24/23 at 8:15 a.m. revealed one Advantik QS12 (SN: S15099341) and one Advantik QS11 (SN: 59481)cryostat in use for processing tissues removed during Mohs surgical procedure. 2. Review of the manufacturer's operating manuals revealed the following operating limits: -Avantik QS 12: Temperature range of 5 to 35 degrees Celsius with maximum relative humidity of 60%. -Avantik QS 11: Temperature range of 5 to 35 degrees Celsius with maximum relative humidity of 60%. 3. Review of the laboratory's environmental records for 2021, 2022, and 2023 revealed no documented monitoring of ambient temperature and humidity. 4. Interview with the office manager and lead histotechnician on 8/24 /23 at 1:30 p.m. confirmed the laboratory did not document ambient temperature and humidity in the area the cryostats were used to process tissues removed during Mohs surgical procedures in 2021, 2022, and 2023.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the procedure manual, review of patient testing logs, and staff interview, the laboratory failed to ensure potassium hydroxide (KOH) reagent, used for fungal patient testing, was not used past the expiration date in 2021, 2022, and 2023 (seven patients reported). The findings include: 1. Observation of the laboratory on 8/24/23 at 8:40 a.m. revealed 2 bottles of 10% KOH (Lot: 0084-00) reagent with an expiration date of 9/30/21 in use for fungal scraping examination. 2. Review of the policy titled "Potassium Hydroxide (KOH) Examination" revealed the following statement: "4.3.3 Do not use reagents after expiration date" 3. Review of the patient testing log titled "KOH/Scabies log" revealed patient testing on 12/22/21, 6/14/22, 1/10/23, 2/13/23, 6/14/23, 7/25/23, and 8 /9/23. 3. Interview with the office manager and lead histotechnician on 8/24/23 at 1:30 p.m. confirmed the KOH reagents observed in the laboratory were used for fungal examination of seven patient specimens after the reagent expiration date of 9/30/2021 until the date of the survey (8/24/23).
D6168	TESTING PERSONNEL CFR(s): 493.1487

	The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on observation of the laboratory, staff interviews and review of personnel records, laboratory testing personnel performing high complexity inking and mapping of tissue removed during Mohs surgical procedure failed to meet the regulatory education requirements (Refer to D6171).
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality

	control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on observation of the laboratory, interview with the lead histotechnician and laboratory director, review of personnel records, and interview with the office manager and lead histotechnician, the two testing personnel (TP) performing high complexity testing failed to meet the regulatory education requirements. The findings include: 1. Observation of the laboratory on 08/24/23 at 8:05 a.m. revealed reagents, stains, and inks in use for performing histopathology procedures for tissues obtained by the Mohs surgical procedure. 2. Interview with the lead histotechnician and laboratory director on 08/24/23 at 8:15 a.m. revealed that tissue is brought to the lab by the Mohs surgeon and the histotechs (TP3 and TP4) perform inking and mapping of the tissue. 3. Review of testing personnel records revealed TP3 and TP4 did not have the required education to perform high-complexity testing. 4. Interview with the office manager and lead histotechnician on 8/24/23 at 1:30 p.m. confirmed the histotechs performing inking and mapping of tissues removed during the Mohs surgical procedure did not meet the required regulatory education requirement to perform high-complexity testing.