Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2135992	10/24/2023
Name of Provider or Supplier	**Street Address, City, State**	
Highlander Dermatology Llc	16650 W Bluemound Rd, Ste B800, Brookfield, WI	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Item 1 Based on surveyor review of laboratory records and interview with the nurse manager, staff A, the laboratory did not retain the lot number and expiration date for the chemical reagents and stains used for Mohs surgery slide staining on the Histopro414 slide stainer for seventeen of seventeen months reviewed in 2022 and 2023. Findings include: 1. Review of the "Highlander Dermatology Chemical Reagent Log" showed no documentation of chemical reagent or stain lot number and expiration date information from June 17, 2022 through October 24, 2023. 2. Interview with the staff A on October 24, 2023, at 10:35 AM confirmed the laboratory did not retain the lot number and expiration dates from the chemical reagents and stain used for Mohs surgery slides. Item 2 Based on surveyor review of laboratory records and interview with the nurse manager, staff A, the laboratory did not retain the date of service for Mohs surgery patients for three of fourteen days of patient testing. Findings include: 1. Review of the cryostat temperature log showed Mohs surgery performed on the following days: June 17, 2022 July 14, 2022 September 9, 2022 October 21, 2022 November 18, 2022 December 16, 2022 February 10, 2023 March 10, 2023 April 7, 2023 May 5, 2023 June 2, 2023 July 28, 2023 September 8, 2023 October 6, 2023 2. Review of the "Mohs Log" showed no documentation of which patients had Mohs testing on December 16, 2022, February 10, 2023, and March 10, 2023. 3. Interview with the staff A on October 24, 2023, at 10:35 AM confirmed the laboratory did not retain the date of service for Mohs surgery patient testing.
D5407	PROCEDURE MANUAL

	CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on survey review of laboratory procedures and interview with the nurse manager, staff A, the laboratory director did not sign and date one of one Mohs surgery procedures prior to patient testing. Findings include: 1. Review of laboratory procedures showed no documentation the laboratory director reviewed and signed the "Mohs Quality Assurance and Quality Control" procedure. 2. Interview with the staff A on October 24, 2023, at 10:00 AM confirmed the laboratory director did not sign and date new Mohs procedures prior to patient testing.
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 surveyor review of cryostat temperature logs and procedures, and interview with the nurse manager, staff A, the laboratory did not define an acceptable temperature range that was consistent with the manufacturer's acceptable range for one of one Leica CM15105 cryostats used for Mohs surgery. Findings include: 1. Review of "Temperature Log for Cryostat" showed no established temperature range for the cryostat used for Mohs patient testing. 2. Review of laboratory procedures showed no procedure available that pertained to the range used on the cryostat for Mohs patient testing. 3. Interview with the staff A on October 24, 2023, at 10:35 AM confirmed the laboratory had not defined an acceptable range for the Leica CM15105 cryostat.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the nurse manager, staff A, the laboratory did not record the time of specimen receipt in the laboratory for

	three of nine Mohs tissue specimens from two of four randomly reviewed patients records. Findings include: 1. Review of laboratory records including patient logs, Mohs maps and patient test reports for four randomly chosen patients showed staff did not record the time of specimen receipt in the laboratory for three of nine Mohs tissue samples for: Patient 1: one of three tissue specimens collected Patient 2: date of service March 10, 2023; one of two tissue specimens collected Patient 2: date of service October 6, 2023; one of four tissues specimens collected 2. Interview with staff A on October 24, 2023, at 10:35 AM confirmed the laboratory did not record the time of specimen receipt in the laboratory for three of nine Mohs tissue specimens reviewed.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor review of laboratory records and procedure manuals and interview with the nurse manager, staff A, the director did not provide overall management and direction in accordance with 493.1445 of this subpart. Findings include: 1. The laboratory director did not ensure that the quality assessment programs are established and maintained to identify failures in quality as they occur. See D6094 2. The laboratory director did not ensure that appropriate procedures were available for testing personnel and that procedures were approved. See D6106
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and Mohs slides and interview with the dermatologist and nurse manager, staff B and staff A, the laboratory director did not ensure that quality assessment programs were established and maintained to identify failures in quality as they occur during patient testing for two of four patients reviewed. Findings include: 1. Review of laboratory records for Mohs testing showed a "Slide Log Mohs" and a " Mohs Log". Further review showed the case numbers on the logs did not match for the following patients reviewed: Patient 1: Slide log was labeled as case 14, Mohs log was labeled as case 15. Patient 2: Slide log was labeled as case 51, Mohs log was labeled as case 57. Patient 3: Slide log was labeled as case 75, Mohs log was labeled as case 85. Patient 4: Slide log was labeled as case 75A, Mohs log was labeled as case 81 and 82. 2. Interview with staff B on October 24, 2023, at 10:40 AM stated the "Slide Log Mohs" was a patient tracking device for the facility by staff B to track number of patients and staff B would renumber the Mohs slides after the cases based on the "Slide Log Mohs". 3. Review of Mohs slides for patients 1-4 revealed the following: Patient 1: Mohs slides labeled with "Mohs Log" information of case number 15 and first slide of group included date of service of

	September 9, 2022, and "slide Log Mohs" case number of 14, with the slide log number placed in the corner of the other slides. The information did match the slide log and Mohs log in this case. Patient 2: Mohs slides labeled with "Mohs Log" information of case number 105 and the first slide of the group included date of service of March 10, 2023, and "Slide Log Mohs" case number of 51, with the slide log number placed in the corner of other slides. Further review of this patient showed Mohs case number 105 was performed on October 6, 2023, and corresponded with "Slide Log Mohs" case number 94. Mohs case 57 was performed on March 10, 2023, and corresponds with "Slide Log Mohs" case number 51. Slide case number 94 slides were pulled and had the appropriate number of slides to correlate with Mohs case number 57. Patient 3: Mohs slides labeled with "Mohs Log" information of case number 85 and first slide of group included date of service of June 2, 2023, and "Slide Log Mohs" number of 81, with the slide log number placed in the corner of the other slides. The information did match the slide log and Mohs log in this case. Patient 4; Mohs slides labeled with "Mohs Log" information and case number 81 and first slide of group included date of service of June 2, 2023, and "Slide Log Mohs" number of 75A, with the slide log number 75A placed in the corner of the other slides. Slides were not relabeled as 75A for case 82. 4. Interview with staff A on October 24, 2023, at 11:10 AM, confirmed the laboratory director did have an established quality assessment program to identify failures in quality as they occur.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on surveyor review of procedures and interview with the nurse manager, staff A, the laboratory director did not ensure that approved procedures were available to testing personnel for one of one new tests performed in the laboratory. Findings include: 1. Review of the procedure manual showed one Mohs procedure available titled "Mohs Quality Assurance and Quality Control" that was not signed or dated by the laboratory director. further review showed no other procedures available for Mohs testing in the laboratory. 2. Interview with staff A on October 24, 2023, at 10:00 AM confirmed one procedure for Mohs testing was available but not signed or dated by the laboratory director. Further interview confirmed no additional procedures were available for Mohs testing.