Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0953867	08/29/2023
Name of Provider or Supplier	**Street Address, City, State**	
Ou Health Partners Dermatology	Nicholson Tower, Oklahoma City, OK	

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	The recertification survey was performed on 08/29/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the senior clinical manager, ethics and compliance officer, and Mohs histology technician during an exit conference performed at the conclusion of the survey.
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 a review of records, written policies and procedures, and interview with the Mohs histology technician, the laboratory failed to have a written policy to assess the competencies of the technical consultants, technical supervisors, and general supervisor, based on the position responsibilities as listed in Subpart M, for two of two persons. Findings include: (1) A review of the laboratory policy and procedure manual identified no evidence of a policy for assessing the competency of the technical consultants, technical supervisors, and general supervisor, based on position responsibilities, including the frequency of the assessments; (2) A review of the Form CMS-209 (Laboratory Personnel Report) and personnel records for competency assessments performed during the review period of August 2021 through the current date identified competencies, based on job responsibilities, had not been performed for two of two persons listed as technical consultants and technical supervisors; and one of two persons listed as general supervisor; (3) The findings were reviewed with the Mohs histology technician who stated on 08/29/2023 at 11:10 am, a policy had not been written and competencies had not been performed as shown above.
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 a review of records and interview with the Mohs histology technician, the laboratory failed to ensure the temperatures for two of two Leica CM-1850 cryostats were documented three of seven days of patient testing reviewed from 07/15/2022 through 07/27/2023. Findings include: (1) On 08/29/2023 at 09:35 am the Mohs histology technician stated the laboratory performed slide interpretation of frozen sections of tissues obtained during Mohs surgical procedures using two Leica CM-1850 cryostats (denoted by the laboratory as Cryostat #1 and Cryostat #2) to prepare the specimens; (2) A review of temperature records for patient testing performed from 07/15/2022 through 07/27/2023 identified the temperatures of the cryostats had not been documented three of seven days of patient testing (07/15/2022, 07/19/2022, and 07/22/2022); (3) The records were reviewed with the Mohs histology technician who stated on 08/29/2023 at 12:40 pm, the temperatures had not been documented as shown above.
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 and interview with the Mohs histology technician, the laboratory failed to ensure that one of one expired Chlorazol Black E reagent and one of five expired tissue marking dyes were not available for use. Findings include: CHLORAZOL BLACK E (1) On 08/29/2023 at 09:20 am the Mohs histology technician stated KOH (potassium hydroxide) analysis was performed as a PPM (provider performed microscopy) procedure using Chlorazol Black E or KOH reagent; (2) Observation of room 1936, where the testing was performed, identified one bottle of EDM3 Solutions HealthLink Chlorazol Black E reagent, lot #1120 with an expiration date of 04/20/2023 that appeared to be available for use; (3) The findings were reviewed with the Mohs histology technician who stated on 08/29/2023 at 09:30 am, the expired Chlorazol Black E reagent was available for use. GREEN TISSUE MARKING DYE (1) On 08/29/2023 at 09:35 am the Mohs histology technician stated the laboratory performed slide interpretation of frozen sections of tissues obtained during Mohs surgical procedures; (2) Observation of the Mohs laboratory on 09/29 /2023 at 09:37 am identified one bottle of Stat Lab Medical Products Green Tissue Marking Dye, lot #123468 with an expiration date of 06/30/2023 that appeared to be

	available for use; (3) The findings were reviewed with the Mohs histology technician who stated on 08/29/2023 at 09:40 am, the expired Green Tissue Marking Dye was available for use.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's maintenance instructions, and interview with the Mohs histology technician, the laboratory failed to perform the manufacturer's required weekly maintenance procedures for two of two cryostats during the review period of December 2022 through July 2023. Findings include: (1) On 08/29/2023 at 09:35 am the Mohs histology technician stated the laboratory performed slide interpretation of frozen sections of tissues obtained during Mohs surgical procedures using two Leica CM-1850 cryostats (denoted by the laboratory as Cryostat #1 and Cryostat #2) to prepare the specimens; (2) A review of the operator's manuals for the cryostats identified the following: (a) Cryostat #1 - Section 10.31 under "General Maintenance" stated, "Once a Week - Apply a drop of oil to the plastic coupling"; (b) Cryostat #2 - Section 9.31 under "General Maintenance" stated, "Once a Week - Apply a drop of oil to the plastic coupling". (3) A review of maintenance logs for Cryostat #1 and Cryostat #2 from December 2022 through the July 2023 identified the weekly maintenance had not been documented as performed between: (a) 12/02/2022 and 01/04/2023 (b) 01/04/2023 and 02/03/2023 (c) 02/03/2023 and 03 /03/2023 (d) 03/03/2023 and 04/07/2023 (e) 04/07/2023 and 05/05/2023 (f) 05/05 /2023 and 06/02/2023 (g) 06/02/2023 and 07/07/2023 (4) The findings were reviewed with the Mohs histology technician who stated on 08/29/2023 at 11:40 am, the laboratory had been performing the oiling procedure for both cryostats monthly instead of weekly.