Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0953867	07/26/2021
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 07/26/2021. The findings were reviewed with the Mohs technician at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the Mohs technician, the laboratory failed to verify the accuracy of KOH (Potassium Hydroxide) analysis and Ectoparasite examinations at least twice annually. Findings include: (1) On 07/26/2021 at 09:45 am, the Mohs technician stated to surveyor #1 the laboratory performed KOH analysis and Ectoparasite examinations; (2) Surveyor #2 reviewed records between 05/23/2019 through 07/26/2021, which showed the testing had not been verified for accuracy at least twice annually in 2019, 2020, and 2021; (3) Surveyor #2 reviewed the records with the Mohs technician who stated on 07/26/2022 at 2:25 pm, KOH analysis and Ectoparasite examinations had not been verified for accuracy at least twice annually as indicated 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, manufacturer's instructions, observation, and interview with the laboratory manager, the laboratory failed to ensure materials were stored as required for 5 of 5 months. Findings include: (1) On 07/26/2021 at 10:25 am, the Mohs technician stated to the surveyors the MART-1/Mean-A (Melanoma Marker) Ab-3 (Cocktail) stain was performed in the laboratory beginning 06/19/2020; (2) On 07/26/2021 at 10:40 am, surveyor #2 observed the following stored in the laboratory refrigerator: (a) MART-1/Melan-A Ab-3 stain (3) The Mohs technician stated to surveyor #2 on 07/26/2021 at 10:25 am, MART-1/Mean-A Ab-3 is used as a melanocyte differentiation antigen to recognize cells of melanocytic differentiation and the diagnosis of melanoma; (4) Surveyor #2 reviewed the manufacturer's package insert for the stain. Under "Storage and Stability", the manufacturer stated, "Ab with sodium azide is stable for 24 months when stored at 2-8 C."; (5) Surveyor #2 then reviewed the temperature records from 07/28/2020 through 12/17/2020 and identified the materials were being stored at temperatures colder than 2 degrees C (Celsius) or warmer than 10 degrees C for 8 of 86 days reviewed as follows: (a) July - Days 28,29,30 were documented at temperatures that were colder than 2 degrees C (b) August -Day 18 was documented at a temperature warmer than 10 degrees C (c) October- Day 7 was documented at a temperature colder than 2 degrees C (d) November - Days 21, 23 were documented at temperatures that were colder than 2 degrees C (e) December 0 Day 17 was documented at a temperature colder than 2 degrees C (6) Surveyor #2 reviewed the records with the Mohs technician who stated on 07/26/2021 at 02:40 pm, the refrigerator temperatures were unacceptable for the materials as shown above.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of records and interview with the Mohs technician, the technical consultant failed to ensure evaluations included all moderate complexity testing performed for 6 of 6 testing persons. Findings include: (1) On 07/26/2021 at 09:45 am, the Mohs technician stated to surveyor #1 KOH analysis and Ectoparasite examinations were performed in the laboratory; (2) Surveyor #2 then reviewed personnel records for 6 persons performing KOH examinations and Ectoparasite examinations in the laboratory between 05/23/2019 through 07/26/2021; (3) There was no evidence annual evaluations, performed for the 6 persons, included an assessment of KOH analysis and Ectoparasite examinations; (4) Surveyor #1 reviewed the findings with the Mohs technician, who stated on 07/26/2021 at 02:26 pm the above persons did not have an assessment of KOH analysis and Ectoparasite examinations as indicated above.