Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0695067	11/02/2023
Name of Provider or Supplier	**Street Address, City, State**	
Ttuhsc Dept Of Dermatology	3601 4th Street Suite 4a100, Lubbock, TX	

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 laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended.
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: I. Based on review of the laboratory's records and interview, the laboratory failed to retain the chemical name and concentration (if applicable), manufacturer, lot number, expiration date, received date, and open date of the chemicals and stains used in the laboratory in Mohs processing for two of two years reviewed. Findings follow. A. The reagent log was requested on November 2, 2023 at 1035 in the office but not provided. B. Interview with the LVN on November 2, 2023 at 1035 hours in the office confirmed the laboratory did not maintain a reagent log. II. Based on review of the Mohs test reports and interview, the laboratory failed to retain the Mohs map for four of 11 patients reviewed. Findings follow. A. Review of the Mohs test report showed 4 were missing the maps as listed by case number and date of service: 1. M22-302 06/28 /2022 2. M22-431 09/20/2022 3. M23-320 07/17/2023 4. M23-410 09/18/2023 B. Interview with the LVN on November 2, 2023 at 1215 hours in the office confirmed the Mohs maps were missing for four of the cases selected.
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 review of the manufacturer's instructions, the laboratory's policy and procedure, laboratory logs, patient testing logs, interview, and pre-survey paperwork, the laboratory failed to document the room temperature and humidity of the laboratory for nine out of 56 days of Mohs testing reviewed. Findings follow. A. Review of the Leica CM1860 Instructions for Use, 10/2016, under Technical Data stated, "Operating Temperature range (ambient temperature): 18 to 35 degrees Celsius. All specifications related to temperature of the cooling unit are valid only for an ambient temperature of 22 degrees Celsius and a relative humidity of no more than 60%." B. Review of the laboratory's policy and procedure titled Mohs Lab cryostat and ambient temperature and humidity policy, effective 09/27/2019, stated, "Room temperature for Leica Cryostat should range from 18 degrees Celsius to 35 degrees Celsius and ambient temperature of 22 degrees Celsius and maximum air humidity of 60%." C. Review of the laboratory's Dermatology Mohs Lab form from 05/01/2023 - 09/18/2023 showed missing documentation on the following nine days of Mohs testing: 1. 05/03/2023 2. 05/08/2023 3. 07/18/2023 4. 07/19/2023 5. 07/24/2023 6. 07/25/2023 7. 08/08/2023 8. 08/09/2023 9. 09/12/2023 D. Review of the patient logs showed the following patients were tested: 1. 05/03/2023 M23-205 - M23-211 2. 05/08/2023 M23-212 3. 07/18 /2023 M23-322 - M23-323 4. 07/19/2023 M23-324 - M23-329 5. 07/24/2023 M23-330 - M23-331 6. 07/25/2023 M23-332 - M23-333 7. 08/08/2023 M23-352 - M23-353 8. 08/09/2023 M23-354 - M23-360 9. 09/12/2023 M23-401 - M23-402 E. Interview with the LVN on November 2, 2023 at 1240 hours confirmed after a review of the records, the temperature and humidity were not recorded every day of patient testing. F. Review of the CMS Form 116 showed approximately 450 cases were performed annually.