Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2218596	02/02/2024
Name of Provider or Supplier	**Street Address, City, State**	
Longhorn Dermatology	4900 Bee Creek Rd #101, Spicewood, 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: Based on a review of the laboratory's policies and procedures, laboratory's records, pre-survey paperwork, 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 for the Hematoxylin and Eosin (H&E) stain used in Mohs processing for one of one years reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled Mohs Quality Control Program, Origination date 09/2021, stated under Quality Control of Reagents: "1. Correct labeling of reagents and chemicals should include content and concentration, date received or prepared, date opened, expiration date, and storage temperature. 2. Commercially obtained reagents will be labeled to indicate date received, date opened. The manufacturer's expiration date will be utilized. If no expiration date is on the container, an expiration date of one year from the received date is assigned as the expiration date. 3. Expired reagents are not to be used and are discarded." B. The reagent log was requested on February 2, 2024 at 1055 hours but not provided. Review of the Daily H&E Quality Control Check Log from January to December 2023 showed documentation of the Lot number and Expiration date for Gill's 3 Hematoxylin and Eosin-y with Phloxine stains. Lot number and expiration date were requested for the Alcohol, xylene, and bluing on

	February 2, 2024 at 1200 hours but not provided. C. Review of the CMS Form 116 showed approximately 1000 Mohs stages were performed annually. D. Interview with the technologist on February 2, 2024 at 1200 hours confirmed the findings.
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 review of the laboratory's policies and procedures, accuracy assessments, pre-survey paperwork, and interview, the laboratory failed to perform twice a year accuracy assessments of Mohs for one of two years reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled Mohs Quality Control Program, Origination date 09/2021, stated under Quality Management (QM) for Mohs Surgery: "TWO cases per calendar year by an ASMS or ACMS fellow of Mohs Micrographic Surgery or board-certified Dermatopathologist from an outside laboratory and TWO interdepartmental cases per calendar year PER Mohs surgeon by an ASMS or ACMS fellow of Mohs Micrographic Surgery or a board-certified Dermatopathologist. Two cases (frozen section slides and Mohs map) are selected randomly from the current year by the technician and submitted to an external Mohs surgeon or dermatopathologist and in house MD for outside and inter department quality assurance respectively. The dermatologist reviewing the case will judge whether the sections and staining are adequate and whether the margins are free of tumor. This will be kept on file in the laboratory." B. Review of the accuracy assessments from 2022 and 2023 showed no accuracy assessments performed in 2023. Additional accuracy assessments were requested on February 2, 2024 at 1040 hours but not provided. C. Review of the CMS Form 116 showed approximately 1000 Mohs stages were performed annually. D. Interview with the technologist on February 2, 2024 at 1040 hours confirmed the findings.
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 review of the manufacturer's instructions, laboratory's policies and procedures, preventative maintenance (PM) records, pre-survey paperwork, and interview, the laboratory failed to perform periodic preventative maintenance on the Accu-Scope 3000-LED Microscope used for Mohs testing for two of two years reviewed. Findings follow. A. Review of the Accu-Scope 3000-LED Microscope Series Manual obtained on-line, under Service stated, "Accu-Scope Microscopes are precision instruments which require periodic servicing to keep them performing properly and to compensate for normal wear." B. Review of the laboratory's policy and procedure titled Mohs Quality Control Program, Origination date 09/2021, showed preventative maintenance and microscope were not mentioned. C. Preventative maintenance records were reviewed from 06/05/2021 - 02/02/2024 and

	showed no preventative maintenance records for the microscope available for review. Preventative maintenance records for the microscope were requested on February 2, 2024 at 1130 but not provided. D. Review of the CMS Form 116 showed approximately 1000 Mohs stages were performed annually. E. Interview with the technologist on February 2, 2024 at 1130 hours confirmed there was no PM performed on the microscope.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, pre-survey paperwork, competency evaluations, and interview, the technical supervisor failed to evaluate the competency at least semiannually during the first year the individual tested patient specimens for two of two semi-annual competency evaluations in Mohs testing. Findings follow. A. Review of the laboratory's policy and procedure titled Mohs Quality Control Program, Origination date 09/2021, showed no mention of competency evaluations. B. Review of the pre-survey paperwork titled Laboratory Personnel showed testing personnel #1 (as listed on the CMS form 209) was hired in January 2023. C. Two semi-annual competency evaluations for testing personnel #1 were requested on February 2, 2024 at 1030 hours but not provided. D. Interview with the technologist on February 2, 2024 at 1030 hours confirmed competency evaluations were not performed.