Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2258312	07/08/2026
Name of Provider or Supplier	**Street Address, City, State**	
Clear Creek Dermatology	904 Ford St, Llano, 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 Clear Creek Dermatology laboratory in Llano was found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, CLIA requirements for laboratories as a result of a recertification survey on 07/07 /2026 and recertification is recommended. Standard level deficiencies were cited.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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 review of the laboratory's policies and procedures, reagent log, observation, reagent check log, patient testing logs, and interview, the laboratory failed to ensure chemicals and stains used in the Hematoxylin and Eosin (H&E) stain used to process Mohs specimens had not exceeded their expiration date by three out of 25 days of testing in 2026. Findings follow. A. 1. Review of the laboratory's policy and procedure titled Quality Control Program, reviewed 06/23/2022, under Test Methods, Equipment, Reagents, Materials and Supplies stated, "Reagents, solutions, culture media, controls, calibration materials and other supplies are not used when they have exceeded their expiration dates, have deteriorated or are of substandard quality." 2. Review of the laboratory's policy and procedure titled Laboratory Procedure Manual Histopathology- Mohs Surgery, on page 32 stated, "4.3.3 Do not use reagent after expiration date unless results are checked and satisfactory (i.e. stains)." The statement "unless results are checked and satisfactory" did not align with the regulatory requirements. B. Review of the Reagent Receipt & Quality Control Record log showed Eosin, Lot # 2415233, expiration 06/14/2026 was opened on 11/20/2025. There were no additional entries for Eosin revealing an elapsed expiration of 23 days. C. Surveyor observed on July 7, 2026 at 1115 hours in the storage room two

	containers of Eosin-y in the flammable cabinet: Mercedes Scientific Eosin-y, Lot #2415233, expiration 06/14/2026. No other Eosin-y was observed. D. Review of the Storage of Flammable Reagents Cabinet Check log for the month of June and the first week of July 2026 showed it was checked on 06/25/2026 but the expired Eosin-y was not documented or discarded. The check was not documented the first week of July 2026. E. Review of the Mohs Specimen Log from 06/15/2026- 07/07/2026 showed three days of Mohs testing with expired Eosin-y with 35 cases reported: M26-255 - M26-289. F. Interview with the Office Manager on July 7, 2026 at 1120 hours confirmed the findings.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) (b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section. This STANDARD is not met as evidenced by: I. Based on review of the manufacturer's instructions, laboratory's policies and procedures, preventive maintenance records, pre-survey documents and email, the laboratory failed to establish and follow a preventive maintenance protocol to ensure the performance of the Accu-Scope microscope for one of two years reviewed in 2024 and 2025. Findings follow. A. Review of the Accu-Scope 3000-LED Series Manual under Care and Maintenance stated, "Accu-Scope microscopes are precision instruments which require periodic preventive maintenance to maintain proper performance and to compensate for normal wear. An annual schedule of preventive maintenance by qualified personnel is highly recommended." B. Review of the laboratory's policy and procedure titled Quality Control Program, revised 06/23/2022, under Equipment Maintenance stated, "The Laboratory Director will ensure that periodic equipment maintenance and function checks are performed as required by the manufacturer or determined by the Laboratory Director. Proper records will be maintained to indicate the tests performed." The policy and procedure did not define the frequency of the preventive maintenance of the microscope. C. Review of the preventive maintenance records for 2024 and 2025 showed no preventive maintenance on the Accu-Scope microscope for 2025. Preventive maintenance records for 2025 were requested on July 7, 2026 at 1140 hours but not provided. D. Review of the CMS Form 116 showed an estimated annual test volume of 449 blocks. E. Email from the Office Manager on July 8, 2026 at 0855 hours confirmed the preventive maintenance for the microscope in 2025 was not done. II. Based on review of the manufacturer's instructions, laboratory's policy and procedure, preventive maintenance records, pre-survey documents and email, the laboratory failed to provide documentation of maintenance performed as defined by their own policy using the Avantik Q12 Cryostat used to cut frozen sections for Mohs testing. Findings follow. A. Review of the Avantik QS12 Cryostat Instruction Manual, 5259000 rev 3, under Cleaning and Care at Preventative Maintenance stated, "It is recommended that preventative maintenance is performed on the instrument at least once a year by a qualified service technician." B. Review of the laboratory's policy and procedure titled Quality Control Program under Equipment Quality control for Cryostats stated, "10) Preventive maintenance and grounding checks are done yearly." C. Review of the preventive maintenance records for 2024 and 2025 showed no preventive maintenance on the Avantik QS12 cryostat in 2025. Preventive maintenance records were

	requested on July 7, 2026 at 1140 hours but not provided. D. Review of the CMS Form 116 showed an estimated annual test volume of 449 blocks. E. Email from the Office Manager on July 8, 2026 at 0855 hours confirmed the preventive maintenance for the cryostat in 2025 was not done.