Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2101929	08/21/2024
Name of Provider or Supplier	**Street Address, City, State**	
Canyon Dermatology	1101 4th Avenue, Canyon, 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. Standard level deficiencies were cited.
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 review of the laboratory's policies and procedures, reagent log, interview, and presurvey paperwork, the laboratory failed to retain the open date of the chemicals and stains used in the laboratory in Mohs processing for two of two years reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled Laboratory Procedure Manual Histopathology- Mohs Surgery under 4.3.3 stated "Do not use reagent after expiration date." B. Review of the reagent log from 08/22/2022 - 08/21/2024 was missing the open date of the chemicals and stains. Without the open date, the laboratory cannot ensure reagents were used within their expiration date. C. Interview with the Office Manager on August 21, 2024 at 0945 hours in the breakroom confirmed the laboratory did not retain the open date for the chemicals and stains. D. Review of the CMS Form 116 showed an estimated annual volume of 420 Mohs stages.
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 Mohs accuracy assessments, interview, and presurvey paperwork, the laboratory failed to access accuracy of its Mohs testing for one of two years reviewed. Findings follow. A. Review of the laboratory's accuracy assessment records from 2022 and 2023 showed the 2023 peer reviews did not state the peer agreed with clear margins on the final stage, accurate maps and slides, and slide quality. B. Interview with the Office Manager on August 21, 2024 at 0930 hours confirmed there was no written statement from the peer stating her assessment of the case for the peer reviews in 2023, and the office manager filled in the form showing "matched diagnosis= yes" on the peer review summary. C. Review of the CMS Form 116 showed an estimated annual volume of 420 Mohs stages.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, Mohs logs, presurvey paperwork, and interview, the laboratory failed to follow its own policy to document the number of slides per case for two of two years reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled Laboratory Procedure Manual Histopathology- Mohs Surgery under 3.4 Specimen Handling, Storage, Preservation and Identification stated, "3.4.6 Patient name, site, date, Mohs surgeon and laboratory technician is written on Mohs log, along with total number of slides processed." B. Review of the Mohs logs from 08/22/2022 - 08/21/2024 showed the number of slides per case was not recorded. C. Review of the CMS Form 116 showed an estimated annual volume of 420 Mohs stages. D. Interview with the Office Manager on August 21, 2024 at 1155 hours in the breakroom confirmed the findings.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in

	the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's policies and procedures, pre-survey paperwork, and interview, the laboratory failed to include accuracy assessments for Mohs testing in its procedures for two of two years reviewed. Findings follow. A. Review of the laboratory's policies and procedures did not include accuracy assessments (see D5217). B. Review of the CMS Form 116 showed an estimated annual volume of 420 Mohs stages. C. Interview with the Office Manager on August 21, 2024 at 1152 hours in the breakroom confirmed the findings. II. Based on review of the laboratory's policies and procedures, pre-survey paperwork, and interview, the laboratory failed to include the documentation of its reagents in its procedures for two of two years reviewed. Findings follow. A. Review of the laboratory's policies and procedures did not include the documentation of its reagents (see D3031). B. Review of the CMS Form 116 showed an estimated annual volume of 420 Mohs stages. C. Interview with the Office Manager on August 21, 2024 at 1153 hours in the breakroom confirmed the findings.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, pre-survey paperwork, prior CMS 116, and interview, the laboratory director failed to approve, sign, and date the Laboratory Procedure Manual Histopathology- Mohs Surgery prior to use for eight of eight months reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled Laboratory Procedure Manual Histopathology- Mohs Surgery was signed and dated by the previous Laboratory Director 01/11/2017. B. Review of the CMS Form 209 revealed the current Laboratory Director. C. Review of the prior CMS 116 for the change in Laboratory Director was effective 12/01/2023 (elapsed time 8 months 21 days). D. Interview with the Office Manager on August 21, 2024 at 1150 hours in the breakroom confirmed the procedure was not signed by the current laboratory director.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

	This STANDARD is not met as evidenced by: Based on review of the patient test reports, Mohs map, and slides, the laboratory failed to include the correct number of stages for one of 10 Mohs test reports reviewed. Findings follow. A. Review of 10 randomly selected Mohs cases showed Mohs case 062024-09 was missing a STAGE in the visit notes which also served as the patient test report. Review of the visit notes for the Mohs Surgery only documented 1 stage: "STAGE 1: The area was prepped with Betadine. A rim of normal appearing skin was marked circumferentially around the lesion. The area was infiltrated with local anesthesia. An incision at a 45 degree angle following the standard Mohs approach was done and the specimen was harvested as a microscopic controlled layer. Hemostasis was achieved with electrocautery. The specimen was oriented, mapped and placed in 1 block. Each section was then chromacoded and processed in the Mohs lab using the Mohs protocol and submitted for frozen section. Frozen section analysis showed: no residual tumor seen. Histology: There were no malignant cells seen in the sections examined." B. Review of the Mohs map showed there were 2 stages, STAGE I showed a squamous cell carcinoma, and STAGE II was clear. C. Review of the case slides showed a total of two slides labeled for STAGE I and II. D. Interview with the Office Manager on August 21, 2024 at 1145 hours in the laboratory confirmed the patient note was incorrect based on the Mohs map and slides.