Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2101929	03/23/2021
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
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: Review of facility peer review records, and interview of facility personnel found that the laboratory failed to verify the accuracy of results for two of two peer reviews for Mohs surgical procedures in 2020. The findings included: 1. Review of the document titled Peer reviews (for 2019 and 2020) found the laboratory provided columns for documenting the case sent for review, the performing physician and the reviewing physician, as well as a column for matched diagnosis. Information recorded for 2019 and 2020 peer reviews on this document: PID 021519-07 Site L Cheek performed by Testing person 2, Peer review testing person 1 date reviewed 02/19/2019, Matched PID 052419-02 Site Ldist pretib performed by Testing person 2, Peer review testing person 1, date reviewed 05/29/2019, Matched PID 013120-22 Site L inflat neck performed by Testing person 2, Peer review Testing Person 1date reviewed 02/04 /2020, no documentation of results matching or not PID 101620-04 Site L sup helix performed by Testing person 2, Peer review Testing Person 1, date reviewed 10/21 /2021 no documentation of results matching or not Review of the Pathology reports for the cases submitted for peer review found: PID 021519-07 Site L Cheek performed by Testing person 2, Peer review testing by outside physician, date reviewed 02/19/2019, Matched PID 052419-02 Site Ldist pretib performed by Testing person 2, Peer review testing person 1, date reviewed 05/29/2019, Matched PID 013120-22 Site L inflat neck performed by Testing person 2, Peer review Testing Person 1date reviewed 02/04/2020, no documentation of results matching or not PID 101620-04 Site L sup helix performed by Testing person 2, Peer review Testing Person 1, date reviewed 10/21/2021 no documentation of results matching or not Additional records were requested to support the peer review records but not

	provided. Interview of office personnel conducted on March 23, 2021 at 09:00 AM found that testing person 1 left in the summer of 2019 to assume the responsibilities of a political appointment. He contracted with a local physician to continue offering Mohs surgical procedures in his absence. She went on to say that these were "the records faxed from California and this was all she had".
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: Observations made during the tour of the facility found that the laboratory failed to ensure that expired marking dyes were not available for use in patient testing. The findings included: 1. Observations made during the tour of the laboratory conducted March 23, 2021 at 10: 03 AM found expired tissue Marking Dyes StatLab Red tissue Marking Dye lot 076456 expiration 2021-02-01 StatLab Blue Tissue Marking Dye lot 076195 expiration 2021-01-01 and CDI Tissue Marking Dye lot 6137 expiration 2017-10-01 2. Interview of the office staff conducted on March 23, 2021 learned that she had no idea what they were used for or if they were used in patient testing.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control records, patient test records, MOHS procedures and interview of facility personnel, the laboratory failed to document the negative and positive reactivity of quality control slides for Hematoxylin and Eosin (H and E) staining on each day of patient testing between January 2019 and March 2021. The findings included: 1. Based on review of H and E stain quality control charts between January 2019 through December 2020 the laboratory documented acceptability of stain reactivity using the initials CD in the column titled acceptable for each date represented. There was no key to define the CD response. Review of the 2021 H&E Stain Quality Control Chart found 0 entries of quality control documentation. The form contained information regarding the lot numbers for the Hematolylin (lot 1915730 expiration 06/12/21) and Eosin (lot 2019607 expiration 07/28/2022). 2. Review of patient test records for 2021 found patients tested with no documentation of quality control procedures as follows: January 29, 2021 - 15 patients had Mohs surgical procedures with no documentation of negative and positive staining reactivity for the H and E stains. March 5, 2021 - 11 patients had Mohs surgical procedures with no documentation of negative and positive staining reactivity for the H and E stains. March 19, 2021 - 14 patients had Mohs surgical procedures with no documentation of negative and positive staining reactivity for the H and E stains. 3. Review of the

	procedure titled MOH's section procedure found: " once slide is stained and coverslipped check quality under Mohs scope and deliver to testing personnel for review ". There was no legend of symbols used for quality control responses in the procedure. 4. Interview of office staff conducted on March 23, 2021 at 10:28 AM confirmed that testing person returned from his political assignment in March 2021, with his first surgical date on March 5, 2021. She went on to explain that she assumed the CD documented in the acceptable column of the H& E stain charts was the initials of the testing personnel. She continued to say the she had no other documents that might document intended reactivity of negative and positive control tissues each day of patient testing for H and E staining.
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 testing personnel files, and interview of facility personnel, the Technical Supervisor failed to evaluate and document personnel competency at least semiannually during the first year the individual tests patient specimens for one of two testing personnel performing Mohs histopathology procedures. The findings included: 1. Review of personnel files found testing person two (hired January 2019) had no record of semiannual competency evaluation during the first year of testing. 2. Interview of the office staff conducted on March 23, 2021 at 10:15 AM confirmed that competency assessments had not been performed and documented at least semiannually for the first year of testing for testing person two.
D6128	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 annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of testing personnel files, and interview of facility personnel, the Technical Supervisor failed to evaluate and document personnel competency at least annually after the first year the individual tests patient specimens for one of two testing personnel performing Mohs histopathology procedures. The findings included: 1. Review of personnel files found testing person two (hired January 2019) had no record of annual competency evaluation in 2020. 2. Interview of the office staff conducted on March 23, 2021 at 10:15 AM confirmed that competency assessments had not been performed and documented at least annually for each year after the first year of testing for testing person two.