Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2101929	10/06/2022
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
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 procedures, H&E quality control records, patient test records and interview of facility personnel, the laboratory failed to document the negative and positive reactivity of quality control slides for Hematoxylin and Eosin (H &E) staining on each day of patient testing between June 2021 and August 2022. THIS IS A REPEAT DEFICIENCY FROM THE MARCH 2021 INSPECTION. The findings included: 1. Review of the procedure titled 493.1705 QUALITY CONTROL ASSESSMENT FOUND: "1. Quality control values are documented every working day. 2. These values are reviewed individually and consecutively by the doctor. 3. If a failure of a control value occurs, the source of the failure is determined and corrective measures will be taken and documented. 4. There are logs for all equipment (microscope, room temperature, centrifuge and Mohstech equipment). These are to be updated each working day and reviewed by the doctor." 2. Based on review of H and E stain quality control records between June 2021 and September 22, 2022 found 0 entries of quality control reactivity 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). No additional records were available for review. 3. Review of patient test records found 741 patient specimens tested with no documentation of quality control procedures as follows: June 23, 2021 - 17 patients had Mohs surgical procedures with no documentation of negative and positive staining reactivity for the H and E stains. June 24, 2021 - 25 patients had Mohs

surgical procedures with no documentation of negative and positive staining reactivity for the H and E stains. July 15, 2021 - 22 patients had Mohs surgical procedures with no documentation of negative and positive staining reactivity for the H and E stains. July 16, 2021 - 12 patients had Mohs surgical procedures with no documentation of negative and positive staining reactivity for the H and E stains. August 23, 2021 - 24 patients had Mohs surgical procedures with no documentation of negative and positive staining reactivity for the H and E stains. August 24, 2021 - 20 patients had Mohs surgical procedures with no documentation of negative and positive staining reactivity for the H and E stains. September 22, 2021 - 24 patients had Mohs surgical procedures with no documentation of negative and positive staining reactivity for the H and E stains. September 23, 2021 - 22 patients had Mohs surgical procedures with no documentation of negative and positive staining reactivity for the H and E stains. October 20, 2021 - 21 patients had Mohs surgical procedures with no documentation of negative and positive staining reactivity for the H and E stains. October 21 - 26 patients had Mohs surgical procedures with no documentation of negative and positive staining reactivity for the H and E stains. November 17, 2021 - 22 patients had Mohs surgical procedures with no documentation of negative and positive staining reactivity for the H and E stains. November 18, 2021 - 32 patients had Mohs surgical procedures with no documentation of negative and positive staining reactivity for the H and E stains. December 15, 2021 - 30 patients had Mohs surgical procedures with no documentation of negative and positive staining reactivity for the H and E stains. December 16, 2021 - 35 patients had Mohs surgical procedures with no documentation of negative and positive staining reactivity for the H and E stains. January 19, 2022 - 28 patients had Mohs surgical procedures with no documentation of negative and positive staining reactivity for the H and E stains. January 20, 2022 - 20 patients had Mohs surgical procedures with no documentation of negative and positive staining reactivity for the H and E stains. February 23, 2022 - 36 patients had Mohs surgical procedures with no documentation of negative and positive staining reactivity for the H and E stains. February 24, 2022 - 20 patients had Mohs surgical procedures with no documentation of negative and positive staining reactivity for the H and E stains. March 23, 2022 - 9 patients had Mohs surgical procedures with no documentation of negative and positive staining reactivity for the H and E stains. March 24, 2022 - 27 patients had Mohs surgical procedures with no documentation of negative and positive staining reactivity for the H and E stains. April 20, 2022 - 12 patients had Mohs surgical procedures with no documentation of negative and positive staining reactivity for the H and E stains. April 21, 2022 - 31 patients had Mohs surgical procedures with no documentation of negative and positive staining reactivity for the H and E stains. May 25, 2022 - 14 patients had Mohs surgical procedures with no documentation of negative and positive staining reactivity for the H and E stains. May 26, 2022 - 31 patients had Mohs surgical procedures with no documentation of negative and positive staining reactivity for the H and E stains. June 16, 2022 - 37 patients had Mohs surgical procedures with no documentation of negative and positive staining reactivity for the H and E stains. July 20, 2022 - 13 patients had Mohs surgical procedures with no documentation of negative and positive staining reactivity for the H and E stains. July 21, 2022 - 42 patients had Mohs surgical procedures with no documentation of negative and positive staining reactivity for the H and E stains. August 18, 2022 - 47 patients had Mohs surgical procedures with no documentation of negative and positive staining reactivity for the H and E stains. September 21, 2022 - 42 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 September 22, 2022 at 9:53 AM confirmed that she had no other records available for review that might document intended reactivity of negative and positive control tissues each day of patient testing for H and E staining.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: The laboratory director failed to establish and maintain the quality control program for Hematoxylin and Eosin staining of tissue specimens to include intended reactivity of positive and negative staining materials used in Histopathology testing. (see D5473)