Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2080177	08/31/2023
Name of Provider or Supplier	**Street Address, City, State**	
Waco Dermatology	6609 Sanger Ave, Waco, 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: I. Based on review of the laboratory's reagent log, observation, interview, and pre-survey paperwork, the laboratory failed to retain the chemical name and concentration (if applicable), manufacturer, lot number, expiration date, received date, open date of the chemicals and stains used in the laboratory for the Hemotoxylin and Eosin (H&E) stain used in Mohs processing for two of two years reviewed. Findings follow. A. Review of the reagent log from 08/31/2021 - 08/31/2023 showed one chemical (RGA 95) logged in the last two years. B. During a tour of the laboratory on August 31, 2023 at 1200 surveyor observed no chemicals or stains available for use in the laboratory. C. Interview with the Clinic Manager on August 31, 2023 at 1030 hours in the office confirmed the findings. Further interview with the Clinic Manager on August 31, 2023 at 1205 hours in the office acknowledged chemicals were either expired or close to expiration and were thrown out prior to inspection. D. Review of the CMS Form 116 showed an estimated annual test volume of 240 stages. II. Based on review of Mohs testing logs, pre-survey paperwork, and interview, the laboratory failed to retain the Mohs testing logs for two of two years reviewed. Findings follow. A. Mohs testing logs from 08/31/2021 - 08/31/2023 were requested on August 31, 2023 at 1015 but not provided. B. Review of the CMS Form 116 showed an estimated annual test volume of 240 stages. C. Interview with the Clinic Manager on August 31,

	2023 at 1015 in the office acknowledged the histotech did not leave the testing logs in the laboratory and added there was a gap in testing from 07/20/2022 - 04/17/2023, and Mohs testing was performed once per month.
D3041	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting. This STANDARD is not met as evidenced by: Based on review of patient test reports, slides, interview, and pre-survey paperwork, the laboratory failed to retain Mohs test records for at least 10 years from the report date for one of two reports older than two years reviewed. Findings follow. A. Random review of two Mohs cases from 09/25/2014 and 11/16/2014 showed one test report was unavailable for review. B. Interview with the Clinic Manager on August 31, 2023 at 1115 hours in the office acknowledged if a patient has not been seen in the last seven years, the file is sent to offsite storage. C. Review of the CMS Form 116 showed an estimated annual test volume of 240 stages.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure, accuracy assessments, and interview, the laboratory failed to establish written policies and procedures for Mohs peer review to include clear margins on final stage, accurate maps and slides, and slide quality for documentation from the peer in Mohs testing to show agreement for two of two events reviewed. A. Review of the laboratory's policies and procedures showed they did not have a quality assurance policy. B. Review of the accuracy assessments by peer review showed no documentation from the peer on the agreement of the Mohs testing performed for the 05/16/2023 and 04/18/2023 events, or whether there were clear margins on the final stage, accurate maps and slides, and slide quality. C. Interview with the Clinic Manager on August 31, 2023 at 1000 hours in the office acknowledged the peer reviews were done by conference call and there was no documentation from the peer showing agreement for the Mohs testing, and the documentation for accurate diagnosis was performed by the Clinic Manager.