Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2080177	02/18/2020
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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Review of the CMS form 209 Laboratory Personnel Report, policies and procedures, personnel files and interview of facility personnel found that the laboratory did not have a procedure for assessing the competency of all testing personnel and supervisors involved in histopathology testing. The findings included: 1. Review of the CMS 209 Laboratory Personnel Report found the Laboratory Listed 2 Testing Personnel , one general supervisor, 1 technical supervisor performing high complexity procedures. 2. Review of policies and procedures found no written policy to assess the competency of all testing personnel, consultants and supervisors. 3 . competency assessment records for testing person 2 (hired January 2019) listed on the CMS report 209 were requested on February 18, 2020 at 3:32 PM. 4. Interview of the histotechnician conducted on February 18, 2020 at 3:35 PM confirmed that the laboratory did not have a written policy to assess the competency of the consultants, supervisors and testing personnel. She went on to say that testing person 2 was hired in January and no semiannual competency assessments had been performed.
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 the laboratory's policies, quality assurance records from 2016 through 2018 and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessment for MOHS testing. Findings included: 1. A review of the laboratory's policy and procedure manual found no written policy for performing twice annual accuracy assessment of MOHS testing. 2. Records of twice annual accuracy assessment for 2018 and 2019 were requested but not provided. 3. Interview of the histotechnician conducted on February 18, 2020 at 2: 46 PM confirmed that no records were available for review that would ensure that the laboratory verified the accuracy of their work at least twice each year in 2018 and 2019. She stated they did it, but do not have record of it.
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, 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 2018 and February 2020. The findings included: 1. Based on review of H and E stain quality control logs between January 2018 and March 2019 the laboratory documented acceptability of stain reactivity using a "+" in the column titled acceptable for each day of the month and the initials of the individual responsible for reading slides. There was no key to define the + response. 2. Review of the procedure titled MOH's section procedure found: " once sllide 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. 3. Interview of the histotechnician conducted on February 18, 2020 at 2:29 PM confirmed that the laboratory does not document intended reactivity of negative and positive control tissues each day of patient testing for H and E staining.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment 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: Based on review of laboratory policies, and staff interview, it was revealed the laboratory director failed to ensure a quality assessment program was established and maintained to detect failures in quality of performance for histopathology testing. The finding were as follows: 1. Review of laboratory policies and procedures found no quality assurance plan specific to the laboratory services provided. 2. Interview of the

	histotechnician confirmed that the laboratory did not have a quality assurance plan specific to laboratory services.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: The laboratory director failed to ensure there was a procedure in place to assess the competency all testing personnel involved in preanalytic, analytic and postanalytic testing of histopathology specimens. (See D5209)
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 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 histotechnician conducted on February 18, 2020 at 3:32 PM confirmed that competency assessments had not been performed and documented at least semiannually for the first year of testing for testing person 1.