Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2140968	11/09/2018
Name of Provider or Supplier	**Street Address, City, State**	
Warren Clinic Dermatology And Mohs Surgery	6565 S Yale, Ste 1200, Tulsa, OK	

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 initial survey was performed on 11/09/18. The findings were reviewed with the laboratory director at the conclusion of the survey. The laboratory was found to be in compliance with standard-level deficiencies cited.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory director, the laboratory failed to perform the manufacturers required maintenance procedures on the cryostat. Findings include: (1) At the beginning of the survey, the laboratory director stated the laboratory prepared frozen sections using the Avantik QS12 UV Cryostat. The sections were stained with H&E (Hematoxylin & Eosin), then reviewed microscopically by a pathologist; (2) Later during the survey, surveyor #2 reviewed the manufacturer's instructions for performing maintenance procedures on the cryostat, which were: (a) Every 6- 8 weeks - Shut the instrument off (3) Surveyor #2 reviewed maintenance records from 06/05/18 through the day of the survey (11/09/18); (a) There was no evidence the shut down had been performed. (4) Surveyor #2 reviewed the maintenance records with the laboratory director, who stated there was no evidence the shut down of the instrument had been performed.
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 a review of records and interview with the laboratory director, the laboratory failed to document the reactivity of the H&E (Hematoxylin & Eosin), stain each day of testing. Findings include: (1) At the beginning of the survey, the laboratory director stated the laboratory performed microscopic interpretations of histology (Mohs and skin biopsies) specimens that had been stained with H&E (Hematoxylin & Eosin) stain; (2) Surveyor #2 reviewed test records for 98 days of patient testing (microscopic interpretations) performed from 06/05/18 through 11/08/18. There was no evidence that the reactivity of the stain had been observed for acceptability for the 4 of the 98 days as follows: (a) 06/14/18 (b) 06/27/18 (c) 07/31/18 (d) 08/15/18 (3) Surveyor #2 reviewed the findings with the laboratory director, who stated the reactivity of the stain was observed for acceptability on each patient slide, but had not been documented.
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 a review of records and interview with the laboratory director, the laboratory failed to ensure test reports included the address of the testing location. Findings include: (1) At the beginning of the survey, the laboratory director stated to the surveyors, the laboratory performed frozen sections from skin biopsies; which were stained with H&E (Hematoxylin and Eosin) and examined microscopically for diagnosis; (2) The surveyors reviewed 4 frozen pathology reports. The dates of testing were 08/13/18, 10/01/18, 10/31/18, and 11/05/18. The address of the laboratory where the testing was performed was not included on the reports; (3) The surveyors reviewed the findings with the laboratory director who stated the address of the laboratory was not included on the reports.