

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2140968	(X3) Date Survey Completed 10/30/2020
Name of Provider or Supplier Warren Clinic Dermatology And Mohs Surgery	Street Address, City, State 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 recertification survey was performed on 10/30/2020. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director and the histotechnician at the conclusion of the survey.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the histotechnician, the laboratory failed to verify the accuracy of slide interpretations at least twice annually. Findings include: (1) On 10/30/2020 at 10:00 am, the histotechnician stated to the surveyor, the laboratory microscopic interpretations of H&E (Hematoxylin and Eosin) stained slides from procedures on dermatologic biopsies (skin biopsies and elliptical excisions) and tissues removed during Mohs surgery. The tissue would then be observed microscopically; (2) On 10/30/2020 at 11:30 am, the histotechnician stated to the surveyor the accuracy of the microscopic interpretations was performed by sending cases to another physician for evaluation; (3) The surveyor reviewed records for 2019 and to date in 2020, and identified the accuracy of the dermatologic biopsy slide interpretations had not been verified twice annually in 2019 and to date in 2020 as follows. The testing had not been verified for accuracy after April 2019; (4) The surveyor reviewed the records with the histotechnician who stated on 10/30/2020 at 12:15 pm, the accuracy of the dermatologic biopsy interpretations had not been verified twice in 2019 and to date in 2020.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p>

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:

Based on a review of records, observation, and interview with the histotechnician, the laboratory failed to ensure that staining procedures were not performed with expired staining materials. Findings include: (1) On 10/30/2020 at 10:00 am, the histotechnician stated to the surveyor, the laboratory performed H&E (Hematoxylin and Eosin) staining procedures on skin biopsies and Mohs tissues. The tissue would then be observed microscopically; (2) On 10/30/2020 at 10:30 am, the surveyor observed the current stains in use and identified the following expired stains available for use: (a) Three bottles of Avantik Biogroup Gill 3 Hematoxylin (lot #066599) had a manufacturer's expiration date of November 2019; (b) One bottle of Avantik Eosin Working Solution (lot #H05-21 had a manufacturer's expiration date of 03/06/2020; (c) Three bottles of EKI Oil Red O Stain Solution in Propylene Glycol (lot #1813620) had a manufacturer's expiration date of 05/18/2019. (3) The surveyor showed the stains to the histotechnician, who stated to the surveyor on 10/20/2020 at 10:35 am, the EKI Oil Red O Stain Solution was not routinely used in staining procedures, but along with the other 2 stains, was available for use.