

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0676326	(X3) Date Survey Completed 11/30/2020
Name of Provider or Supplier Southwestern Dermatology	Street Address, City, State 8315 S Walker Ave, Oklahoma City, 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 11/30/2020. The findings were reviewed with the office administrator, office manager, and histotechnician during an exit conference performed at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, policy and procedure, and interview with the histotechnician, the laboratory failed to follow its microscope maintenance procedure during 2 of the 6 months reviewed. Findings include: (1) On 11/30/2020 at 10:00 am, the histotechnician stated to the surveyor the laboratory prepared frozen sections using the Avantik Cryostat. The sections were stained with H&E (Hematoxylin & Eosin), then reviewed microscopically by the pathologist; (2) The surveyor reviewed the procedure contained in the laboratory procedure manual titled, "MICROSCOPE" which stated: (a) "1. The microscope should be covered at the close of every day" (b) "2. Take extra care to keep stage of the microscope clean" (c) "3. Wipe eye pieces and lenses with lens cloth" (d) "4. Change bulbs as needed and have regular service contracts performed" (e) "5. Document daily, monthly care" (3) The surveyor then reviewed microscope maintenance for 6 months (January 2020 through June 2020). It was identified for 2 of 6 months the microscope maintenance had not been documented as performed: (a) March 2020 - 1 of 7 days (i) 03/11/2020 (b) June 2020 -</p>

1 of 7 days (i) 06/30/2020 (4) The surveyor reviewed the records with the histotechnician who stated on 11/30/2020 at 11:25 am, the microscope maintenance had been performed but not documented as indicated above.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on a review of records, manufacturer's instructions, and interview with the histotechnician, the laboratory failed to ensure the cryostat was stored as required by the manufacturer for 6 of 10 months. Findings include: (1) On 11/30/2020 at 10:00 am, the histotechnician stated to the surveyor the laboratory prepared frozen sections using the Avantik Cryostat. The sections were stained with H&E (Hematoxylin & Eosin), then reviewed microscopically by the pathologist; (2) The surveyor reviewed the manufacturer's requirement for humidity which stated, "at a max. rel. humidity of 60%"; (3) The surveyor then reviewed humidity records for 10 months (January 2020 through October 2020). It was identified that documented humidity readings were greater than 60% on days of patient testing for 6 of 10 months reviewed as follows: (a) May 2020 - 2 of 9 days (i) 05/21/2020- 64% (ii) 05/27/2020 - 61% (b) June 2020 - 2 of 9 days (i) 06/04/2020- 62% (ii) 06/30/2020 - 65% (c) July 2020 - 2 of 4 days (i) 07/01/2020 - 64% (ii) 07/29/2020 - 63% (d) August 2020 - 1 of 9 days (i) 08/04/2020 - 63% (e) September 2020 - 1 of 10 days (i) 09/01/2020 - 63% (f) October 2020 - 1 of 6 days (i) 10/08/2020 - 62% (4) The surveyor reviewed the records with the histotechnician who stated on 11/30/2020 at 11:10 am the cryostat had not been stored according to manufacturer's instructions as listed above.

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 patient test reports and interview with the histotechnician, the laboratory failed to ensure test reports reflected accurate patient information for 1 of 5 patient reports. Findings include: (1) On 11/20/2020, the surveyor reviewed 5 patient test reports and identified the reports did not accurately reflect the following

information: (a) Report #5 - A Mohs procedure was performed with the results reported on 08/07/2019: (i) The patient's name on the report did not match the patient log book. (2) The surveyor reviewed the report with the histotechnician. The histotechnician stated on 11/20/2020 11:30 am the patient report did not reflect accurate information as indicated above.