

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0914808	(X3) Date Survey Completed 09/19/2019
Name of Provider or Supplier James B Stewart Jr Md	Street Address, City, State 3705 W Memorial Road, Suite 101, 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 09/19/19. 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.
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 the procedure manual, and interview with the histotechnician, the laboratory failed to follow a written policy for ensuring policies and procedures were reviewed annually. Findings include: (1) At the beginning of the survey, the surveyor reviewed the laboratory's "Mohs Micrographic Laboratory Procedure Manual." A policy, titled "Review Policy" stated, "This procedure manual is reviewed by the laboratory director annually and at other times as required by major changes in procedures or other circumstances affecting performance of the test;"(2) The surveyor then identified the procedure manual review documentation. The laboratory director had not reviewed and signed the procedure manual since 12/10/15; (3) The surveyor reviewed the procedure manual with the histotechnician who stated to the surveyor the procedure manual had not been reviewed and signed after 12/10/15.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper</p>

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, manufacturers' instructions, and interview with the histotechnician, the laboratory failed to ensure the manufacturers' environmental specifications were met for the cryostats. Findings include: (1) At the beginning of the survey, the histotechnician stated to the surveyor the laboratory prepared slides from frozen sections of dermatological biopsy specimens (vertical sections) and from Mohs surgical specimens. The slides were then stained with H & E (Hematoxylin and Eosin), dried, coverslipped, and microscopically examined for diagnosis by the laboratory director; (2) The histotechnician also stated to the surveyor the frozen sections were made using 2 cryostats: (a) Cryostat #1: Thermo Scientific CryoStar NX50 (b) Cryostat #2: Avantik QS 11UV Cryostat (3) The surveyor reviewed the manufacturers' operator manuals for the cryostats and identified the following humidity required for optimal operation: (a) Cryostat #1: The manufacturer required a relative humidity of less than 60%, up to 31 degrees C (Centigrade). In addition, the manual stated, "Performance may deteriorate when operated outside this range."; (b) Cryostat #2: The manufacturer required a relative humidity of less than 60%. (4) The surveyor reviewed records from January 2018 through the day of the survey and could not find documentation the humidity of the testing area had been monitored, as follows: (a) 2018: 176 of 176 days when patient testing was performed (b) 2019: 131 of 131 days when patient testing was performed (5) The surveyor reviewed the findings with the histotechnician, who stated to the surveyor the laboratory had not monitored the humidity of the laboratory as listed above.

D5433

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on a review of records, written policies, and interview with the histotechnician, the laboratory failed to follow their microscope maintenance protocol. Findings include: (1) At the beginning of the survey, the histotechnician stated to the surveyor the laboratory prepared slides from frozen sections of dermatological biopsy specimens (vertical sections) and from Mohs surgical specimens. The slides were then stained with H & E (Hematoxylin and Eosin), dried, coverslipped, and microscopically examined for diagnosis by the laboratory director using the Leica double-headed microscope; (2) The surveyor reviewed the "Mohs Micrographic Laboratory Procedure Manual" and identified the microscope maintenance was to be

performed on the first Monday of each month; (3) The surveyor then reviewed monthly maintenance records from January 2018 through the survey and could not locate documentation the microscope maintenance had been performed during 1 of the 21 months reviewed (February 2019) on 13 days of patient testing; (4) The surveyor reviewed the findings with the histotechnician who stated to the surveyor there was no documentation the microscope monthly maintenance had been performed as listed above.