

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2045476	(X3) Date Survey Completed 07/20/2018
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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
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 lack of the twice annual verification records, an interview with the Moh's histotechnologist, the laboratory did not perform twice annual verification for patient slides performed for Moh's surgery. Findings Include: On July 20, 2018 at approximately 11:30 AM, the Moh's histotechnologist confirmed that the laboratory failed to perform and have available documentation to verify the accuracy of the interpretation of Moh's surgery slides at least twice per year for 2016 & 2017. This is a repeat citation from the surveys of May 5, 2014 and May 16, 2016.</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 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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of temperature records and an interview with the Moh's histotechnologist, the laboratory failed to monitor and document the cryostat</p>

	<p>temperature. Findings Include: On July 25, 2018, at approximately 11:15 am, it was confirmed with the Moh's histotechnologist that the laboratory failed to monitor and document the temperature and humidity for the Leica, Cryostat instrument for February 2017 through September 2017 and November 2017. And January, March and May 2018. Approximately 66 patient specimens were tested and reported for Moh's Surgery during this time.</p>
<p>D5417</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's observation of the reagents used for Moh's slide testing and KOH slides, and an interview with the Moh's histotechnologist, the laboratory failed to discontinue the use of expired histology reagents. Findings Include: It was confirmed with the Moh's histotechnologist on July 20, 2018 at approximately 11:15 am, that the laboratory failed to discard the expired reagents: Hematoxylin - Lot 153233 - expired 7/20/16, Eosin Lot # 339144 - expired 7/2017 and Fungal Stain Lot # K122m3 expired 2/2015. Approximately 132 patient specimens were tested and results released during that time.</p>
<p>D5433</p>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory procedure manual and an interview with the Moh's histotechnologist, the laboratory failed to have a complete maintenance protocol or procedure for histopathology. Findings Include: On June 20, 2018, at approximately 11:30 AM, it was confirmed by the Moh's histotechnologist that the laboratory failed to have a procedure available for maintenance service for the Fume hood and Microscope to include the interval between service performance.</p>
<p>D5473</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(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.</p>

	<p>This STANDARD is not met as evidenced by: Based on a review of records and an interview with the Moh's histotechnologist, the laboratory did not perform and document the quality control acceptability of the Hemotoxlyin and Eosin stain used for histopathology slides: Finding included; It was confirmed with the Moh's histotechnologist on July 20, 2018 at approximately 11:15 AM that the laboratory failed to perform and document the acceptability of the Hemotoxlyin an Eosin Stains performed on the following days of testing: January 18, 2017, February 8, 2017 March 1, 15, 2017 April 5, 26, 2017 May 10, 2017 June 7, 21, 2017 July 12, 2017 August 2, 30, 2017 September 13, 2017 October 12, 25, 2017 Approximately 168 patient slides were tested and results reported for Moh's surgery during that time.</p>
<p>D5791</p>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of procedures and confirmed in an interview with the Moh's histotechnologist, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and correct problems for the analytic phase of patient testing for Moh's surgery.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor findings and an interview with the Moh's histotechnologist, the director failed to ensure that: 1) The POC from the survey of May 16, 2016 was maintained. 2) The QC and QA programs for histopathology was maintained. Refer to D6093 and D6094 This is a repeat citation from the surveys of May 16, 2016.</p>
<p>D6093</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of QC records and confirmed in an interview with the Moh's</p>

histotechnologist on the day of the survey, the laboratory director failed to ensure that the QC program for histopathology was followed to assure quality laboratory services. Refer to D5413, D5417 and D5473

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 a review of procedures and confirmed in an interview with the Moh's histotechnologist at the time of the survey, the director failed to: 1) perform twice annual verification for Moh's surgery slides; and 2) have a procedure for microscope and Fume hood maintenance and schedule, 3). Refer to: D5217, D5433 and D5791

This is a repeat citation from the surveys of May 16, 2016.