

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0931734	(X3) Date Survey Completed 06/12/2018
Name of Provider or Supplier Josiane Lederman Md Pc	Street Address, City, State 116 Lamberts Lane, Staten Island, NY	
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
D3009	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on the laboratory survey and an interview with the Moh's processor, the laboratory failed to notify HHS and the approved accreditation program within 30 days of any changes in Ownership. Name, Location or Director. Finding include; It was confirmed during a telephone conversation with the Moh's surgeon on June 14, 2018, at approximately 4:00 pm that the laboratory director on record had left in November of 2017 and a new Moh's surgeon had begun and is not the director. The laboratory failed to notify the State Agency and HHS that they no longer had a director for Moh's surgery.</p>
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 proficiency test verification records and an interview with the Moh's processor, the laboratory failed to verify the accuracy of the Moh's slide procedure. Findings Include: On June 12, 2018, at approximately 11:15 AM the Moh's processor confirmed that the laboratory failed to perform twice annual verification for</p>

the Moh's slide procedure performed for the year 2017 through the date of this survey. Approximately 100 patient specimens were tested and reported for the Moh's surgery slide procedure performed.

D5400

ANALYTIC SYSTEMS
CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:
Based on surveyor's review of records and an interview with the Moh's processor, the laboratory failed to monitor and evaluate the overall quality system and prevent problems from occurring for the following: 1. Ensure that the laboratory discontinued the use of expired QC and calibrator materials. Refer to D5417; 2. Ensure that a complete and approved procedure manual is available to the individuals responsible for all aspect of the testing process. Refer to D5433.

D5417

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

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 surveyor's observation of the reagents used for Moh's slide testing and an interview with the Moh's processor, the laboratory failed to discontinue the use of expired histology reagents. Findings Include: It was confirmed with the Moh's processor on June 12, 2018 at approximately 11:15 am, the laboratory failed to discard the expired reagents: Hematoxylin - Lot 48853 expired 7/2017, Lot # 049406 expired 4/2018 and Eosin Lot 3 F102-20 expired 4/18118. Approximately 100 patient specimens were tested and results released during that time.

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 the laboratory procedure manual and an interview with the Moh's processor, the laboratory failed to have a complete procedure manual for histopathology. Findings Include: On June 12, 2018, at approximately 11:30 AM, it was confirmed by the Moh's processor that the laboratory failed to have maintenance procedures for the following: 1) Leica Cryostat in use, 2) Fume hood, 3) Microscope

D6076

LABORATORY DIRECTOR

CFR(s): 493.1441

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.

This CONDITION is not met as evidenced by:

1) Based on surveyor review of the laboratory's records and interview with the Moh's processor, the laboratory failed to have a director who meets the qualification requirements for performing the professional component of Moh's surgery.

FINDINGS: 1. The new Moh's surgeon began reading and reporting the Moh's surgery slides results in November 2017. The Moh's processor confirmed on June 12, 2018 at approximately 11:30 AM that the professional component of Moh's surgery was being read by a Mohs surgeon. 2. During a telephone conversation with the Moh's surgeon, the Moh's surgeon stated that she was not the director, therefore the laboratory has been operating without a qualified laboratory director since November 2017 to provide overall management of the laboratory and assure compliance with Quality Control and Quality Assurance requirements. Refer to D6078, D6094, D6102

D6078

LABORATORY DIRECTOR QUALIFICATIONS

CFR(s): 493.1443

The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory

director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification.

This STANDARD is not met as evidenced by:

Based on surveyor review of the laboratory's records and interview with the Moh's processor, and review of the CMS 209 Personnel Form, it was determined that the laboratory did not have a Laboratory Director (LD) from November 2017 through the date of survey. Findings: On June 14, 2018, the laboratory emailed the survey documents to this surveyor. The documents were not completed at the time of the survey and needed signatures. Upon receipt of the forms, it was observed that the director listed was not the director of records. At 3:58 PM on June 14, 2018, in a telephone conversation with the Moh's surgeon, Dr. M.H., specifically stated that she did sign the 116 form as the laboratory director but she refused and wanted her name removed as the director of the laboratory which is a high complexity laboratory. Therefore, the laboratory did not have a qualified director at the time of this survey.

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 lack of procedures and an interview with the Moh's processor, the laboratory director failed to ensure that the laboratory's QA program (pre-analytical, analytical and post-analytical) was maintained as part of the laboratory's overall quality systems program . Refer to D5217, D5417, and D5433

D6102

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on a review of personnel records and an interview with the Moh's processor, the laboratory director failed to ensure that appropriate training was documented for two of two new testing personnel who perform high complexity Moh's surgery tissue processing.