

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 03D2147354	<b>(X3) Date Survey Completed</b> 05/24/2019
<b>Name of Provider or Supplier</b> J M Dermatology	<b>Street Address, City, State</b> 3124 Willow Creek Rd, Prescott, AZ	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3000</b>	<p><b>FACILITY ADMINISTRATION</b> CFR(s): 493.1100</p> <p>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.</p> <p>This CONDITION is not met as evidenced by: Based on the number and severity of deficient practices identified during the survey, the Condition: Facility Administration was found to be not met. The laboratory failed to establish safety policies and procedures, failed to retain pathology test reports and failed to retain patient slides in a manner that ensures proper preservation. See D3011, D3041 and D3043 for findings.</p>
<b>D3011</b>	<p><b>FACILITIES</b> CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on lack of procedures for review and interview with the facility personnel, the</p>

laboratory failed to establish safety procedures to ensure protection from physical, chemical, biochemical and electrical hazards, and biohazardous materials. Findings include: 1. The laboratory began patient testing on June 4, 2018, with an approximate annual test volume of 240. The laboratory reads and interprets slides in conjunction with Mohs testing in the sub-specialty of Histopathology. 2. No safety procedures related to Mohs testing were presented for review during the survey conducted on May 24, 2019. 3. The facility personnel confirmed that the laboratory failed to establish safety procedures related to Mohs testing.

**D3041**

**RETENTION REQUIREMENTS**  
CFR(s): 493.1105(a)(6)

Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting.

This STANDARD is not met as evidenced by:  
Based on lack of patient test reports for review, review of laboratory procedure logs and interview with the facility personnel, the laboratory failed to retain pathology test reports for ten years after the date of reporting. Findings include: 1. The laboratory performs patient testing under the specialty of Pathology, with an approximate annual test volume of 240. The laboratory performs the Mohs procedure and uses a log to track each specimen tested, in addition to, utilizing an electronic medical record (EMR) system for maintaining patient records and test reports. 2. The facility personnel stated that it is the practice of the laboratory to document the Mohs test results on a Mohs map and Mohs Flow Sheet which are scanned into the patient's electronic record. 3. No documentation of a Mohs test report (Mohs map and/or Mohs Flow Sheet) was provided for review during the survey for seven out of ten patients: MO13-2018, MO26-2018, MO37-2018, MO55-2018, MO58-2018, MO68-2018 and MO02-2019. 4. The facility personnel confirmed that the laboratory failed to retain the Mohs test reports, original records or scanned copy, for the patients referenced above.

**D3043**

**RETENTION REQUIREMENTS**  
CFR(s): 493.1105(a)(7)

The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen.

This STANDARD is not met as evidenced by:  
Based on lack of histopathology slides for review, review of patient logs for Mohs testing and interview with the facility personnel, the laboratory failed to retain histopathology slides for at least 10 years from the date of examination. Findings include: 1. The laboratory began patient testing on June 4, 2018, with an approximate annual test volume of 240. The laboratory reads and interprets slides in conjunction with Mohs testing in the sub-specialty of Histopathology. 2. No histopathology slides

	<p>were presented for review during the survey for 10 out of 10 patient records reviewed: MO13-2018, MO05-2018, MO42-2019, MO26-2018, MO37-2018, MO55-2018, MO58-2018, MO68-2018, MO02-2019, and MO10-2019. 3. The facility personnel stated that the slides could not be located at the time of the survey.</p>
<p><b>D5203</b></p>	<p><b>SPECIMEN IDENTIFICATION AND INTEGRITY</b> CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by: Based on lack of policies and procedures presented for review and interview with the facility personnel, the laboratory failed to establish written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen throughout the testing process. Findings include: 1. No documentation was presented for review to indicate the laboratory established written policies and procedures that ensure positive identification and optimum integrity of a patient's tissue specimen from the time of collection through completion of testing and reporting of results. 2. The facility personnel confirmed that the laboratory failed to provide documentation of the policy and procedure indicated above.</p>
<p><b>D5291</b></p>	<p><b>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1239(a)</p> <p>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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on lack of written Quality Assessment policies and procedures and interview with the facility personnel, the laboratory failed to establish policies related to accuracy verification for histopathology testing performed by the laboratory. Findings include: 1. The laboratory performs slide interpretation for Mohs testing under the sub-specialty of Histopathology, with an approximate annual test volume of 240. 2. No documentation was presented during the survey to indicate the laboratory had an established policy related to the verification of accuracy process for the testing indicated above, including but not limited to, information specific to the frequency of the review, number of cases reviewed, individual or laboratory performing the review and a remedial action plan in the event of a noted discrepancy. 3. The facility personnel confirmed that the laboratory failed to have an established written policy in place at the time of the survey for the verification of accuracy process for histopathology testing performed by the laboratory.</p>
<p><b>D5311</b></p>	<p><b>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</b> CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of</p>

the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:  
Based on lack of written policies and procedures for review and interview with the facility personnel, the laboratory failed to establish policies and procedures for patient preparation, specimen collection, specimen labeling, specimen storage and preservation, specimen processing, and specimen acceptability and rejection. Findings include: 1. The laboratory began patient testing on June 4, 2018, with an approximate annual test volume of 240. The laboratory reads and interprets slides in conjunction with Mohs testing in the sub-specialty of Histopathology. 2. No documentation was presented for review during the survey to indicate the laboratory had established policies in place for patient preparation, specimen collection, specimen labeling, specimen storage and preservation, specimen processing, and specimen acceptability and rejection, with regard to Mohs testing. 3. The facility personnel confirmed that the laboratory did not have the above referenced policies and procedures in place at the time of the survey.

**D5391**

**PREANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242.

This STANDARD is not met as evidenced by:  
Based on lack of Quality Assessment (QA) documentation and interview with the facility personnel, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the preanalytic systems. Findings include: 1. No written QA policies and procedures specific to the preanalytic systems were presented for review during the survey. 2. The facility personnel confirmed that the laboratory could not produce evidence of established preanalytic QA policies at the time of the survey.

**D5401**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(a)

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.

This STANDARD is not met as evidenced by:  
Based on lack of a written procedure manual for review and interview with the facility personnel, the laboratory failed to have a written procedure manual for testing performed under the sub-specialty of histopathology. Findings include: 1. The laboratory began patient testing on June 4, 2018, with an approximate annual test

volume of 240. The laboratory reads and interprets slides in conjunction with Mohs testing in the sub-specialty of Histopathology. 2. No evidence of an approved procedure manual for Mohs testing was presented for review during the survey conducted on May 24, 2019. 3. The facility personnel confirmed that the laboratory did not have an approved written procedure for Mohs testing at the time of the survey.

**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 lack of a microscope maintenance policy and interview with the facility personnel, the laboratory failed to have a microscope maintenance policy that indicates specific routine maintenance procedures as well as scheduled preventative maintenance procedures. Findings include: 1. No written microscope maintenance policy was presented for review during the survey with regard to routine and preventative maintenance. At the time of the survey, the laboratory used one microscope for patient testing. 2. The facility personnel acknowledged that there was not a written microscope maintenance policy established by the laboratory at the time of the survey.

**D5787**

**TEST RECORDS**

CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:

Based on lack of patient test records for Mohs testing, patient review of patient Mohs log and interview with the facility personnel, the laboratory failed to maintain a copy of the the Mohs map for seven patients. Findings include: 1. The laboratory performs patient Mohs testing under the sub-specialty of histopathology, with an approximate annual test volume of 101. It is the practice of the laboratory to maintain an electronic medical record system and scan the Mohs test records, including the Mohs map, into the patients' electronic medical chart. 2. Seven out of ten patient test records reviewed during the survey were missing the Mohs maps. The maps were not scanned into the patient's electronic records and the facility personnel could not produce evidence of the maps during the survey. Mohs maps were missing for the following cases: MO13-

2018, MO26-2018, MO37-2018, MO55-2018, MO58-2018, MO68-2018 and MO02-2019. 3. The facility personnel confirmed that the Mohs maps were not presented for review during the survey for the Mohs cases indicated above.

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**

CFR(s): 493.1289(a)(c)

(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.

This STANDARD is not met as evidenced by:

Based on lack of Quality Assessment (QA) documentation and interview with the facility personnel, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the analytic systems. Findings include: 1. No written QA policies and procedures specific to the analytic systems for Mohs testing were presented for review during the survey. 2. The facility personnel confirmed that the laboratory could not produce evidence of an established analytic QA policy at the time of the survey.

**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 review of the laboratory's test reports and interview with the facility personnel, the laboratory failed to list the correct facility name and address on the Mohs maps and Mohs Flow Sheet which are used for reporting patient test results. Findings include: 1. The laboratory performs Mohs testing on patient specimens in the sub-specialty of Histopathology, with an approximate annual test volume of 240. At the time of the survey conducted on May 24, 2019, the laboratory name listed is the CMS Database for CLIA# 03D2147354 was JM Dermatology located at 3198 N Windsong Dr, Prescott Valley, AZ 86314. 2. It is the practice of the laboratory to document the Mohs test results on the Mohs Map and Mohs Flow Sheet. 3. Three out of three Mohs maps reviewed during the survey (#MO05-2018, MO42-2019 and MO10-2019) were missing the name and address of the laboratory where the reading of the slides was performed. 4. Three out of three Mohs Flow Sheets reviewed during the survey (#MO05-2018, MO42-2019 and MO10-2019) listed the incorrect facility name and address. The facility name and address listed on the Mohs Flow Sheet revealed "Associates in Dermatology Care" located at 10900 N. Scottsdale Rd, Ste

	<p>506, Scottsdale, AZ 85254. 5. The facility personnel confirmed that the laboratory name and address were missing on the Mohs map indicated above and the Mohs Flow Sheets referenced above contained the incorrect facility name and address.</p>
<b>D5891</b>	<p><b>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1299(a)</p> <p>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 postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by: Based on lack of Quality Assessment (QA) documentation and interview with the facility personnel, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems. Findings include: 1. No written QA policies and procedures specific to the postanalytic system were presented for review during the survey. 2. The facility personnel confirmed that the laboratory could not produce evidence of an established postanalytic QA policy at the time of the survey.</p>
<b>D6076</b>	<p><b>LABORATORY DIRECTOR</b> 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 the number and severity of deficiencies cited herein, the Condition: Laboratory Director was not met. The laboratory director failed to ensure that a QA program is established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur, see D6094. The laboratory director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process, see D6106.</p>
<b>D6094</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on lack of quality assessment (QA) policies and procedures, the laboratory director failed to ensure that a QA program is established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D5291, D5391, D5791 and D5891 for findings.</p>
<b>D6106</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(14)</p>

The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.

This STANDARD is not met as evidenced by:

Based on lack of an approved procedure manual, the laboratory director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. See D 5401 for findings.