

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D0666037	(X3) Date Survey Completed 02/27/2018
Name of Provider or Supplier Associates In Dermatology Care DbA	Street Address, City, State 11000 N Scottsdale Rd, Ste 120, Scottsdale, AZ	
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
D5293	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assessment (QA) policy and interview with the facility personnel, the laboratory failed to perform and document a quality assessment review as indicated in laboratory policy. Findings include: 1. The laboratory reads and interprets patient slides in conjunction with Mohs testing, with an annual approximate test volume of 101. 2. The laboratory's QA policy states that quality assessment reviews should be conducted at least twice yearly. 3. No documentation was presented for review during the survey conducted on February 27, 2018 to indicate the laboratory had performed and documented a QA review since February 22, 2016. 4. The facility personnel confirmed that the laboratory had not performed a QA review as indicated in policy since February 22, 2016.</p>
D5787	<p>TEST RECORDS CFR(s): 493.1283(a)</p> <p>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).</p>

This STANDARD is not met as evidenced by:
 Based on review of patient test records for Mohs testing, patient slides and interview with the facility personnel, the laboratory failed to: (A) maintain a copy of the the Mohs map for two patients and (B) indicate the correct testing date on the Mohs slides read for dermatopathology testing. 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 Flow Sheet and Mohs map, into the patients' electronic medical chart. A1. Two out of four patient test records reviewed during the survey (J478-2017 and J013-2018) 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. A2. The facility personnel confirmed that the Mohs maps were not presented for review for the Mohs cases indicated above. B1. Review of the Mohs slides for case# J248-2016, performed on 06/22/2016, indicated the slides were incorrectly hand labeled with the date of 6/23/2016. The Mohs patient log indicated that the testing was performed on 06/22/2016. B2. The facility personnel confirmed the correct testing date and agreed that the slides for Mohs case# J248-2016 were labeled with the incorrect test date.

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 review of laboratory policies and procedures, review of patient test records and interview with the facility personnel, the laboratory failed to establish Quality Assessment (QA) policies and procedures for ensuring the accuracy of documentation on the Mohs slides and maintaining the Mohs map in an electronic medical record system (EMR). Findings include: 1. The QA policy reviewed during the survey failed to include a mechanism to monitor the accuracy of the patients' Mohs slides and failed to include a mechanism to monitor the retention of Mohs maps in an electronic record system. See D5787 for findings. 2. The facility personnel confirmed that the laboratory did not have an established policy in place at the time of the survey for monitoring the accuracy and retention of completed Mohs maps and test records.

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 for Mohs testing, test records for Mohs testing and interview with the facility personnel, the laboratory failed to include the test result and correct test date on one test report reviewed during the survey. Findings include: 1. The laboratory performs Mohs testing in the sub-specialty of Histopathology, with an approximate annual test volume of 101. The laboratory utilizes a Mohs Flow Sheet as the test report. The Mohs Flow Sheet contains an area for the physician to document whether or not the margins are clear. 2. One out of four Mohs test reports reviewed during the survey (J248-2016) failed to include the final test result for Mohs. The Mohs Flow Sheet presented for review indicated the procedure involved one stage but there was no indication that the margins were cleared. 3. One out of four Mohs test reports reviewed during the survey (J248-2016) failed to include the correct test date. The Mohs Flow Sheet for case# J248-2016 indicated a date of 6/23/2016, however the testing date as indicated in the Mohs log was 6/22/16. 4. The facility personnel confirmed that the Mohs Flow sheet for case# J248-2016 failed to include the final test result and contained the incorrect testing date.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
 CFR(s): 493.1299(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 postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:
 Based on review of the laboratory's established Quality Assessment (QA) policies and interview with the facility personnel, the laboratory's QA policy failed to include a mechanism to ensure patient test reports are accurate and complete, when maintaining test reports into an electronic record system. Findings include: 1. The QA policy reviewed during the survey failed to include a mechanism to monitor the reporting of test results and ensuring that the laboratory's test reports are accurate and complete. See D5805 for findings. 2. The facility personnel confirmed that the laboratory did not have an established policy in place at the time of the survey for monitoring the accuracy of patient test reports.

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 the number and severity of deficient practices identified during the survey, the laboratory director failed to ensure that a quality assessment program is maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D5293, D5791 and D5891 for findings.