

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D1051078	(X3) Date Survey Completed 05/22/2018
Name of Provider or Supplier Dba Dermatologists Of Birmingham	Street Address, City, State 3570 Grandview Parkway, Suite 100 B, Birmingham, AL	
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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on an interview on 5/22/18 with laboratory personnel #2, during the initial tour of the laboratory, a review of the policy and procedure manual, and an exit interview with laboratory personnel #2 and the office manager, the surveyor determined the laboratory failed to establish a policy and procedure for the KOH (Potassium Hydroxide) microscopic examination. Additionally, the laboratory failed to establish and implement a policy and procedure to verify the accuracy of the microscopic examinations at least twice annually. The findings include: 1. During the initial tour of</p>

the laboratory on 5/22/18, laboratory personnel #2 stated KOH microscopic examinations were performed by two of the office's physicians, during clinic days (non-Mohs days). 2. The policy and procedure manual did not include any policies or procedures for these microscopic examinations, moderate complex procedures. Additionally, there was no policy and procedure for verifying the accuracy (proficiency) of these procedures. 3. During the exit interview at 11:45 AM - 12 Noon on 5/22/18, the office manager and laboratory personnel #2 confirmed there was no policy and procedure for the KOH microscopic examinations.

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 the laboratory's policy and procedure manual, titled Mohs Procedure Manual; including procedures for Mohs days, Mohs technician (job description), and Laboratory procedure, and an interview with the laboratory personnel and office manager, the surveyor determined the laboratory director failed to ensure the laboratory staff was provided with non-conflicting policy and procedures for grossing of tissues. The findings include: 1. A review of the policy and procedure manual, not signed by the laboratory director, on 5/22/18 revealed the following policy and procedural instructions: a. Included in the Mohs days procedure: Mohs tech will gross, cut and stain tissue for examination by physician to check for cancer cells. b. Mohs Technician (job description): opens lab, checks temps, equipment and document proper logs; collects the specimen, transport it to the lab and set-up for physician to gross tissue... c. Included in the example form of an employee evaluation: ...accurate annotation and recording of tissue specimen information d. Included in Lab Procedure: the gross description has been done by the surgeon and all orientation or special instructions have been documented on the map 2. During the initial tour of the laboratory on 5/22/18, laboratory personnel #2 identified herself and lab personnel #1 as performing grossing for the tissues collected on Mohs days (every other Wednesday of the month). At 10:45 AM, laboratory personnel #2 stated she began grossing tissues in the laboratory in March of 2018. 3. It's important to note; neither laboratory staff who was identified as personnel (personnel #1 and #2), who perform grossing, provided educational credentials or training documentation to verify the staff qualified for high complexity testing, grossing. Refer also to D6102. 4. During interviews at 10:45 AM and 11:45 AM, the qualifications for high complexity testing personnel were discussed with the office manager and lab personnel #2. The staff member confirmed the educational credentials and training records necessary for qualification for high complexity testing personnel for #1 and #2 were not maintained in the office or with personnel records. As of Tuesday, May 29 at 11:30 AM, no additional documentation had been received by the State Agency.

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 interviews with laboratory personnel #2 and the office manager and a review of the laboratory's policy and procedure manual, the surveyor determined the laboratory director failed to ensure the laboratory testing personnel presented with educational credentials to verify qualifications for performing high complexity testing (grossing of tissue) was met. Additionally the staff could provide no documentation of training of grossing procedures. The findings include: 1. During the initial tour of the laboratory on 5/22/18, laboratory personnel #2 identified herself and laboratory personnel #1 as performing grossing for the tissues collected on Mohs days (every other Wednesday of the month). During the discussion of grossing procedures at 10:45 AM, laboratory personnel #2 stated she began grossing tissues in the laboratory in March of 2018, after training at another physician's practice. 2. At 10:45 AM, the surveyor requested educational credentials and training documentation for grossing for laboratory personnel #1 and #2 to ensure high complexity testing qualifications were met. No documentation of this training was provided. The office manager presented a certificate of Mohs certification and histology technician for personnel #1. No educational credentials were provided for either of the two. 3. A review of the policy and procedure manual, not signed by the laboratory director, on 5/22/18 revealed the following policy and procedural instructions: a. Included in the Mohs days procedure: Mohs tech will gross, cut and stain tissue for examination by physician to check for cancer cells. b. ...accurate annotation and recording of tissue specimen information 4. During interviews at 10:45 AM and 11:45 AM, the qualifications for high complexity testing personnel were discussed with the office manager and lab personnel #2. The office manager confirmed the educational credentials and training records necessary for qualification for high complexity testing personnel for #1 and #2 were not maintained in the office or with personnel records. In a phone conversation at this time, testing personnel #1 stated she trained many years ago for this type of testing and would provide the State Agency with documentation by Friday, May 25. As of Tuesday, May 29 at 11:30 AM, no additional documentation had been received by the State Agency.

D6106

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(14)

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 a review of the policy and procedure manual, titled Mohs Procedure Manual, and an interview with laboratory personnel #2 and the office manager, the surveyor determined the laboratory director failed to approve of the manual for use in the laboratory, as evidenced by the lack of the director's signature. The findings include: 1. At the surveyor's request, during the initial tour of the laboratory, laboratory personnel provided the policy and procedure manual for the surveyor's review. A review of the manual, titled Mohs Procedure Manual, revealed the laboratory director failed to sign the manual, signifying approval of use by laboratory staff. 2. In an interview on 5/22/18 at 11:45 am - 12 Noon, the surveyor discussed the lack of the director's signature of the policies and procedures (the manual) with

laboratory staff #2 and the office manager, who confirmed the directory had not signed the manual. Patricia Watson, BS, MT (ASCP) Licensure and Certification Supervisor