

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 09D0209146	(X3) Date Survey Completed 10/31/2019
Name of Provider or Supplier Braun Dermatology	Street Address, City, State 3301 New Mexico Avenue Nw, Suite 301, Washington, DC	
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
D2003	<p>ENROLLMENT CFR(s): 493.801(a)(2)(ii)</p> <p>For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1)</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with staff, the histology laboratory did not follow written procedures for biannual peer review of MOHS cases. Findings: 1. The laboratorys written procedure instructs the laboratory to submit three MOHS cases for peer review, for each surgeon, twice a year; 2. In 2018 the laboratory did not perform biannual peer reviews of MOHS cases for each surgeon; 3. In 2019 the laboratory did not perform the first biannual peer review of MOHS cases for each surgeon; and 4. This was confirmed during interview with laboratory staff at approximately 14:00 hours.</p>
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of 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.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on record review and interview, the histology laboratory did not follow its written procedures to document the return of slides referred for consult or followup to determine if slides were returned. Findings: 1. On January 24, 2018 slides were sent out for a second opinion, the slides were prepared from tissue obtained from patient #1 on January 8, 2018. The specimen log includes a space to record the return and date of slides that were sent out of the office. There was no return documentation for the return of these slides in the log; and 2. This was confirmed during interview with the laboratory director at approximately 15:00 hours on the day of survey.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

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.

This STANDARD is not met as evidenced by:
Based on observation and record review, the laboratory written procedure did not ensure that test records for MOHS (MOHS MAP) contain information to ensure reliable patient identification. Findings: 1. The written procedure for the MOHS map does not require the case number for the MOHS surgery to be recorded on the map and the MOHS maps do not have the case number recorded on them.

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:
Based on record review, observation and interview, the laboratory did not update the hematoxylin and eosin (H & E)stain protocol (setup) to ensure the written procedure in the standard operating procedure manual agree with the stain setup posted on the wall above the slide stainer. Findings: 1. The written procedure for performing the H & E stain identified formalin as the first reagent in the stain line and the illustrated chart for the stain line posted on the wall above the slide stainer identified 100% ETOH (ethanol); 2. The written procedure for performing the H & E stain identified

running water (tap) as the third and fourth reagent in the stain line and the illustrated chart for the stain line posted on the wall above the slide stainer identified distilled water; 3. The written procedure for performing the H & E stain identified Eosin as the fifteenth reagent in the stain line and the illustrated chart for the stain line posted on the wall above the slide stainer identified 70% ethanol; 4. The written procedure for performing the H & E stain identified 70% ethanol as the sixteenth reagent in the stain line and the illustrated chart for the stain line posted on the wall above the slide stainer identified eosin; 5. The written procedure for performing the H & E stain did not identify d-limonene as the final reagent, but it was identified as the twenty-first and final reagent on the illustrated chart for the stain line posted on the wall above the slide stainer; and 6. this was confirmed during interview with the laboratory director at approximately 15:00 hour on the day of survey.

D5413

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

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.

This STANDARD is not met as evidenced by:
Based on observation, the laboratory did not maintain room temperature and humidity records as required by the written procedure. Findings; 1. The written procedures stated that the laboratory record the temperature and humidity of the testing area on the QC Log/Lab Temperature and Humidity; and 2. The laboratory did not have a record of the room temperature and humidity for the testing area for 2019 and 2018.

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 record review, the laboratory did not ensure reagents were not used past expiration or substandard quality. Findings: 1. The laboratory did not document the manufacturer, lot number and expiration date of tzanck stain reagents used for patient testing; 2. The laboratory's written procedure did not define how often stains and reagents for the hematoxylin and eosin stain must be changed, rotated, filtered or other activities to maintain quality. The written procedure states that staff will look at the stain in the staining cup for low quality. The lab did not establish time limits to maintain reagents so that they are changed, rotated or maintained at defined intervals before they visually appear to be of substandard quality; and 3. The laboratory 2018 and 2019 records did not document specific duties such as stain changes, filtering and rotation of stains and reagents used for MOHS surgery. The histotechnicians initials were the only recordings on the hematoxylin and eosin stainer cleaning and

maintenance log and did not describe whether or not stains/reagents were changed or rotated.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on record review and interview the histology laboratory did not have preventive maintenance records and procedures to ensure maintenance required by the manufacturer is performed and documented. Findings: 1. The laboratory has two cryostats and one tissue processor; 2. In 2018 annual maintenance was performed (written log) on cryostat #1 (serial number 515019135) record dated 11/4/18. cryostat #2 did not have written preventive maintenance records for 2018 and 2019. The performance of maintenance reported on the annual record may require more than annual frequency, but the manufacturer's manual was not available to determine this; 3. The laboratory records included a daily maintenance record for the cryostat. This record "Cryostat Temp/Cleaning and Maintenance Log dated 2018 did not identify the cryostat maintained, this record did not include regular maintenance tasks recommended by the manufacturer, such as lubrication of the microtome, disinfection, blade replacement and defrosting, if required by the manufacturer; 4. The surveyor could not locate a manufacturer instruction manual that specified required time intervals for each maintenance activity; 5. The laboratory did not have preventive maintenance records for the tissue processor (observed during record review). The manufacturer guidelines for preventive maintenance on the tissue processor could not be located (manufacturer's instruction manual) and may include cleaning, checking or emptying spillage container, vapor trap bottle check and filter replacement; 6. These findings were reviewed with the laboratory director at approximately 15:00 hour on the day of survey. 7. The laboratory's written procedure instructs the laboratory to replace the fume hood filter every three months; the fume hood maintenance log does not include documenting of filter changes; 8. The written procedure instructs lab to perform weekly clearing of microscope, The laboratory did not have weekly preventive maintenance records for the microscope.

D5473

CONTROL PROCEDURES

CFR(s): 493.1256(e)(2)(g)

(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.

This STANDARD is not met as evidenced by:

Based on record review, the MOHS surgery laboratory did not have documentation, for 2018 and 2019, showing that the quality of the hematoxylin and eosin stained slides used for microscopic analysis was evaluated and that this was documented each day of use by the surgeon. The evaluation of the stain includes, but not limited to

appropriate staining characteristics and quality of the stained slides as observed microscopically.

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 record review and observation, the written standard operating procedure manual for histology was not signed and dated to document the laboratory director approval. Findings: 1. The laboratory standard operating procedure manual did not contain a record showing the date of director approval, and signature of director showing approval, this was observed on the day of survey; and 2. The Technical procedure review-Tissue Staining for Frozen MOHS Procedure, page 23, was not completed. The date and reviewer were not entered on the written procedure.