

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D1091651	<b>(X3) Date Survey Completed</b> 12/05/2022
<b>Name of Provider or Supplier</b> Evms Dermatology- Andrews Hall	<b>Street Address, City, State</b> 721 Fairfax Avenue - Suite 200, Norfolk, VA	
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>D0000</b>	An announced CLIA recertification survey was conducted at EVMS Dermatology- Andrews Hall on December 1, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The inspection also included a follow up offsite interview with the practice manager on 12/05/22. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows and includes the Condition under 42 CFR part 493 CLIA Regulations: D6076 - 42 CFR. 493.1441 Condition: Laboratory Director.
<b>D2015</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) documentation, policies, lack of documentation, and interviews, the laboratory failed to retain attestation statements signed by the laboratory director (LD) and testing personnel (TP) for one (1) of five (5) mycology microscopy PT events reviewed. *REPEAT DEFICIENCY Findings include: 1. Review of the laboratory's American Proficiency Institute (API) mycology PT documentation (2021 Events 2-3, 2022 Events 1-3), a total of 5 events, revealed no LD or TP signed attestations for the 2021 Event 3. The</p>

inspector requested to review the LD and TP attestation documentation for the API PT event outlined above. No documentation was available for review. 2. Review of the laboratory's policies revealed a PT Quality Assurance protocol that stated, "Providers and laboratory director will sign attestations and will be reviewed for completion by the laboratory director, all attestations will be retained in PT binder". 3. An interview with the lab director, Mohs surgeon, practice manager, and histotech on 12/1/22 at approximately 4 PM confirmed the above findings.

**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 tour, review of policies, maintenance logs, lack of documentation, and interviews, the laboratory failed to retain documentation of maintenance for one (1) of 1 microscope utilized for patient Mohs histopathology testing in calendar year 2021 per an established protocol. Findings include: 1. During a facility tour at approximately 1:00 PM on 12/01/22, the inspector noted an Olympus Model BX43 Serial #2C40629 microscope in use in the histopathology MOHS specimen processing area. 2. Review of the policies and procedures revealed a quality assessment policy that outlined: "Microscopes will be inspected and serviced on at least a yearly basis by an independent microscope maintenance company or more often if needed due to performance issues." 3. A review of the laboratory's 2021 equipment maintenance logs revealed no record for the Olympus microscope outlined above. The inspector requested to review maintenance records for calendar year 2021. No documentation was available. The practice manager stated on 12/01/22 at approximately 3:30 PM, "We have the maintenance record for the current year but will have to get with the secretary for previous records." 4. Interviews with the lab director, Mohs surgeon, practice manager, and histotech on 12/1/22 at approximately 4 PM and with the practice manager on 12/5/22 at approximately 4:30 PM confirmed the above findings

**D5601**

**HISTOPATHOLOGY**  
CFR(s): 493.1273(a)(f)

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:  
Based on a review of procedures, quality control (QC) records, patient logs, lack of documentation, and interviews the laboratory failed to document daily Hematoxylin

and Eosin (H&E) stain acceptability for eleven (11) of 11 months with six thousand seven hundred twelve (6,712) patient Mohs slides stained/ processed in calendar year 2022. Findings include: 1. Review of the laboratory's Mohs procedure manual revealed a policy (title: "QA/QC Forms") that stated, "Quality control forms are used to document results of Mohs clinical slides. Regular assessment of QC are used to monitor and evaluate procedures in the Mohs histology lab. Daily QC evaluation for routine H&E slides and special requests are signed by the Mohs surgeon who marks them as Satisfactory or Unsatisfactory." 2. Review of the available Mohs laboratory QC records revealed no documentation of daily H&E acceptability from January 3, 2022 up to the date of the survey on December 1, 2022. The inspector requested to review daily H&E QC documentation for the 11 months outlined above. No records for daily QC were available for review. The LD and histotech stated on 12/01/22 at approximately 3 PM "The daily stain QC check is done verbally, it has not been documented to date." 3. Review of the Mohs patient logs from January 2022 through November 2022 revealed 6,712 slides were processed/stained with H&E during the 11 months review timeframe. 4. Interviews with the lab director, Mohs surgeon, practice manager, and histotech on 12/1/22 at approximately 4 PM and with the practice manager on 12/5/22 at approximately 4:30 PM confirmed the above findings.

**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 a review of policies, corrective action logs, lack of documentation, and interviews, the laboratory failed to establish and follow a written Analytic Quality policy for detection and correction of accuracy verification determination for Mohs testing and detection of daily control documentation failures while processing three hundred eight (308) patient Mohs cases from January 3, 2021 to the date of the inspection on December 1, 2022. Findings include: 1. Review of the laboratory's Mohs procedure manual revealed a policy (title: "QA/QC Forms") that stated, "Quality control forms are used to document results of Mohs clinical slides. Regular assessment of QC are used to monitor and evaluate procedures in the Mohs histology lab. Daily QC evaluation for routine H&E slides and special requests are signed by the Mohs surgeon who marks them as Satisfactory or Unsatisfactory." 2. The review of the QA policy revealed no mention of a quality assessment plan for twice annual accuracy monitoring or peer review/proficiency testing for Mohs histopathology. The inspector inquired regarding a policy for twice annual Mohs accuracy review. The lab director (LD) stated on 12/01/22 at approximately 2:00 PM, "We do not currently have an established written protocol for peer review." 3. Review of available corrective action logs for calendar year 2022 revealed no documentation of corrective action for a noted lack of daily stain QC records per the policy outlined above. See D5601. 4. Interviews with the lab director, Mohs surgeon, practice manager, and histotech on 12/1/22 at approximately 4 PM and with the practice manager on 12/5/22 at approximately 4:30 PM confirmed the above findings.

**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:

Based on a review of policies and procedures, quality control (QC) records, patient logs, proficiency testing documentation, corrective action logs, lack of documentation, and interviews the laboratory director failed to: 1. ensure that QC policies for daily Hematoxylin and Eosin stain acceptability were followed for Mohs tissue testing during eleven (11) of 11 months reviewed while six thousand seven hundred twelve patient Mohs slides were stained and processed in calendar year 2022. Cross Reference D6093 2. ensure that quality assessment programs were established /maintained for dermatological/histopathology Mohs laboratory services and failed to identify failures in QC as they occurred noted on the date of the inspection, December 1, 2022. Cross Reference D6094

**D6093**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control 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 procedures, quality control (QC) records, patient logs, lack of documentation, and interviews, the laboratory director failed to ensure that QC policies for daily Hematoxylin and Eosin stain acceptability were followed for Mohs tissue testing during eleven (11) of 11 months reviewed while six thousand seven hundred twelve (6712) patient Mohs slides were stained/processed year to date in calendar year 2022. Cross Reference D5601.

**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 proficiency testing (PT) documentation, Quality Assessment (QA) policies, corrective action logs, lack of documentation, and interviews, the laboratory director (LD) failed to: 1. ensure attestation statement was retained for mycology microscopy's 2021 PT Event 3 per established QA policy, Cross Reference D2015; 2. ensure a policy was written/approved for twice annual accuracy verification determination for Mohs testing as noted on the day of the inspection, December 1, 2022, Cross Reference D5791; and 3. document corrective action for daily QC failures while three hundred eight patient Mohs cases were reported from January 3, 2021 to the date of the inspection on 12/1/22, Cross Reference D5601.