

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2245294	(X3) Date Survey Completed 04/16/2026
Name of Provider or Supplier Warrenton Dermatology Skin Surgery Center	Street Address, City, State 28 Blackwell Park Lane Suite 102, Warrenton, VA	
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
D0000	An announced CLIA recertification survey was conducted at Warrenton Dermatology & Skin Therapy Center on April 16, 2026 by the Virginia Department of Health's Office of Licensure and Certification. 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 Regulation: D5200 -42 CFR. 493.1230 Condition: General laboratory systems.
D5200	<p>GENERAL LABORATORY SYSTEMS CFR(s): 493.1230</p> <p>Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the laboratory's plan of correction (POC) dated 05/15/2024, policies and procedures, proficiency testing (PT) logs, lack of documentation, and interview, the laboratory failed to follow their approved POC and perform Potassium Hydroxide (KOH) accuracy checks twice annually in calendar year 2024 and 2025. See D5217B. **Repeat Deficiency**</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p>

This STANDARD is not met as evidenced by:

A. Based on a review of the laboratory's policies and procedures, proficiency testing (PT) logs, lack of documentation, and interviews, the laboratory failed to follow their established policy and perform one of the two Mohs micrographic surgery twice annual accuracy checks in calendar year 2024. The findings include: 1. Review of the laboratory's policies and procedures revealed a policy, "Proficiency Testing" with the following statements, "Semi-annually, the tech or Risk Manager will send two cases containing the original slides, label it with only surgical case number and send it out for microscopic examination by a Board-Certified Dermatopathologist." 2. Review of the laboratory's PT records for calendar year 2024 revealed 2 Mohs cases were sent out for review in February 2024 and returned to the facility on March 1, 2024. The surveyor requested to review additional peer review cases reviewed in calendar year 2024. The laboratory provided no additional records to review. 3. In an exit interview with the Director of Clinical Operation on April 16, 2026, at 11:45 AM, the above listed findings were confirmed. B. Based on a review of the laboratory's plan of correction (POC) dated 05/15/2024, policies and procedures, proficiency testing (PT) logs, lack of documentation, and interview, the laboratory failed to follow their approved POC and perform Potassium Hydroxide (KOH) accuracy checks twice annually in calendar years 2024 and 2025. ****Repeat Deficiency**** The findings include: 1. Review of the laboratory's PT records for calendar year 2024 and 2025 revealed a lack of documentation of KOH twice annual accuracy checks for calendar year 2024 and 2025. 2. Review of the laboratory's policies and procedures revealed a lack of policy for the performance of KOH twice annual accuracy checks. 3. Review of the laboratory's POC dated 05/15/2024 revealed the following statements, "D5217- The laboratory director decided twice a year when adequate testing is not done to cover the proficiency testing needed, he will provide pictures of KOH to testing personnel to document what they see...Test results will be kept in the KOH /proficiency binder. This will be done twice a year in January and June. The completion for this will be by the last day of June 2024." The surveyor requested to review KOH accuracy checks for calendar years 2024 and 2025. The laboratory provided no documentation for review. 4. In an exit interview with the Director of Clinical Operation on April 16, 2026, at 11:45 AM, the above listed findings were confirmed.

D5417

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

(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 a review of the laboratory's chemical log, policy and procedure manual, MOHS accession log and interview, the laboratory failed to ensure the clearing agent used in staining of MOHS specimens was within manufacturer's expiration date while staining fifty-five (55) Mohs patient specimens on five (5) of 5 patient testing days from September 9, 2024 until September 30, 2024. Record review was from May 1, 2024 until April 16, 2026. The findings include: 1. A review of the laboratory's "Chemical Log Sheet" from May 1, 2024 until April 16, 2026, revealed Avantik clearing agent (lot number 2208760 exp 08/2024) documented as in use from May 31, 2024 through September 30, 2024. There were no other lots of clearing agents listed

as in use on Mohs patient testing days from September 9, 2024 until September 30, 2024. A new lot number of clearing agent (lot number 2417117 exp 06/24/2026) was listed as in use on 10/07/2024. 2. A review of the laboratory's policy and procedure manual revealed a "Monthly Quality Assurance Checklist" with the instructions to complete monthly and to "Mark Y (Yes), N (No), or N/A (Not Applicable)". The checklist listed the following, task, "Our QUALITY CONTROL Policies were performed as specified: All reagents, controls, kits, etc that exceeded their expiration date were discarded." The task was marked with a "Y" and signed on 09/30/2024 by the Laboratory Director. 3. A review of the laboratory's "MOHS Accession Log" revealed 55 Mohs patient specimens were stained from September 9, 2024 until September 30, 2024 while using the expired clearing agent (lot number 2208760 exp 08/2024). 4. In an exit interview with the Director of Clinical Operation on April 16, 2026, at 11:45 AM, the above listed findings were confirmed.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

(a)(1) 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 a review of the laboratory's policy and procedure manual, equipment maintenance logs, manufacturer's operations manual, a laboratory tour and interview, the laboratory failed to follow their established policy to perform and document monthly and annual fume hood maintenance for the Avantik Ductless Fume hood in calendar years 2024, 2025 and up to the date of the survey on April 16, 2026. The findings include: 1. During a tour of the laboratory on April 16, 2026 at 9:00 AM, the surveyor noted an Avantik Ductless Fume Hood in use for the staining of Mohs specimens. Under the fume hood were staining containers labeled as "Eosin, Hematoxylin, Bluing, 95% Alcohol, 100% Alcohol and Clearing agent". On the side of the fume hood, the surveyor noted a clear pouch containing a card for documentation of filter replacement. There was no documentation recorded on the card. 2. Review of the "Advantik Ductless Fume Hood's Installation and Operation" guide revealed the following statements, "The filter installation/replacement history should be maintained using the card supplied in the clear pouch on the side of the blower." and "Maintenance-Enclosure Cleaning: The filters should be checked for system performance and replaced on a regular basis." 3. Review of the laboratory's policies and procedures revealed a policy "Air Vent/Fume Hood Policy", with the statements, "2. Dust air vents monthly, document. 3. Replace filter as required by manufacturer, document. 4. Grounding to be checked and documented annually." 4. Review of the laboratory's equipment maintenance logs revealed a lack of documentation of the monthly and annual fume hood maintenance for calendar 2024, 2025 and up to the date of the survey on April 16, 2026. The surveyor requested to review the documentation of the fume hood maintenance for the above listed timeframe. The laboratory provided no documentation for review. 5. In an exit interview with the Director of Clinical Operation on April 16, 2026, at 11:45 AM, the above listed findings were confirmed.