

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0688909	(X3) Date Survey Completed 10/20/2020
Name of Provider or Supplier Dermatology Consultants Inc	Street Address, City, State 1330 Oak Lane - Suite 101, Lynchburg, 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 on-site CLIA recertification survey was conducted at Dermatology Consultants, Inc. on October 20, 2020 by the Virginia Department of Health's Office of Licensure and Certification. The survey included an entrance interview on 10/05 /2020 and virtual record review conducted on 10/19/2020. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiency cited as follows:
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of policies and procedures, equipment maintenance logs, manufacturer's operations manual, a laboratory tour and an interview, the laboratory failed to document performance of required charcoal cartridge filter replacement maintenance according to the fume hood manufacturer's instructions in calendar years 2018, 2019 and up to the date of the inspection on October 20, 2020. Findings include: 1. Review of the laboratory's policy and procedures manual revealed a quality assurance list of required instrument maintenance duties that included fume hood filter replacement. 2. During the log review, the inspector noted that no filter replacement was documented in calendar years 2018, 2019 or up to the date of the record review on 10/19/20. Documentation of filter replacement was requested. No records were available. 3. Review of the LabConCo Fume Adsorber Operations Manual revealed the statement: "It is important to include filter replacement in routine preventative maintenance schedule. The carbon filter requires routine monitoring and replacement. Time can be used to anticipate saturation or TWA (recommended Exposure Limits expressed as a Time Weighted Average) levels. However, this does</p>

not replace the need for sampling. Consult Labconco technical specialist for an estimate of carbon filter life based on chemical usage. Detector tubes, or analytical instrumentation should always be used to determine concentrations in the carbon filter. The carbon filters must be checked with detector tubes or other means at intervals of 20% of the total estimated filter life. The exception to the 20% recommendation is formaldehyde and any carcinogen or suspected carcinogen. These more hazardous chemicals must be checked at least every 10% of the total estimated time". 4. During a tour of the laboratory on 10/20/20 the inspector noted an Avantik maintenance sticker on the LabConCo Fume hood dated 9/22/17 with due date for next replacement as 9/2018. The inspector requested to review the Avantik field service maintenance report for calendar year 2018 and 2019. The primary lab technician stated, on 10/20/20 at approximately 1:00 PM: "We no longer use Avantik for maintenance of our equipment. We use Tech One Biomedical company. They were here in July 2020. I do not think that they checked or replaced the filters. I do not have documentation." 5. An interview with the primary lab technician, at approximately 3:00 PM, the above listed findings were confirmed.