Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 49D0675231	**(X3) Date Survey Completed** 02/06/2019
Name of Provider or Supplier Evms Department Of Dermatology-Lewis Hall	**Street Address, City, State** 700 West Olney Road Suite 3035, Norfolk, 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 EVMS Dermatology-Lewis Hall on February 6, 2019 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:
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of manufacturer's operation manual, 2017 and 2018 temperature logs, tissue processor instrument maintenance logs, processor run logs and interviews, the laboratory failed to: 1. document that relative humidity percent was acceptable for the Sakura Tissue-Tek patient processing area during twenty-four (24) of 24 months reviewed (Cross reference D5413); 2. document performance of required weekly Tissue-Tek instrument maintenance according to the manufacturer's instructions for fourteen (14) of 14 weeks in calendar year 2018 and failed to document replacement of the tissue processor's charcoal cartridge filter periodically as required during 24 months reviewed while three hundred seventy-three runs were processed. *REPEAT DEFICIENCY (Cross reference D5429).
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 a review of the manufacturer's operation manual, temperature logs, and interviews, the laboratory failed to document that the relative humidity percent (RH%) was acceptable for the tissue processing instrument's operation during twenty-four (24) of 24 months reviewed. Findings include: 1. Review of the Sakura Tissue-Tek Operations Manual revealed a manufacturer's RH% operating environmental requirement with a stated acceptable range of 30-85%. 2. Review of the tissue processing laboratory's daily temperature logs for calendar year 2017 and 2018 revealed humidity monitoring was not recorded in the 24 months reviewed. The inspector requested to review documentation of the humidity monitoring for the tissue processing room. The primary lab technician stated: "at one time the humidity was recorded and I am not sure why it was discontinued". 3. In an exit interview with the practice manager and primary lab technician at 4:30 PM, the above listed findings were confirmed.
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: A. Based on a review of tissue processor operations manual, instrument maintenance logs, and an interview, the laboratory failed to document performance of weekly maintenance according to the manufacturer's instructions for fourteen (14) weeks in calendar year 2018. **REPEAT DEFICIENCY Findings include: 1. Review of the Sakura Tissue-Tek Operations Manual revealed Care of the Equipment Maintenance Instructions in Section 6 that stated: "All the reagents should be replaced or exchanged on a weekly basis". 2. Review of the laboratory's 2018 Sakura Tissue-Tek VIP instrument maintenance logs revealed no documentation of reagent replacement or exchange on the following 14 weeks: 1/15-1/19, 3/26-3/30, 4/9-4/13, 5/7-5/11, 6/1-6/8, 6/25-6/29, 7/9-7/13, 7/30-8/3, 9/10-9/14, 10/15-10/19, 11/26-11/30, 12/3-12/7, 12/10-12/14, 12/17-12/21. The inspector requested to review additional documentation of Xylene, Ethanol, and Formalin reagent replacement and exchange for the weeks outlined above. No records were available. 3. In an exit interview with the practice manager and primary lab technician at 4:30 PM, the above listed findings were confirmed. B. Based on a review of tissue processor instrument maintenance logs, manufacturer's operations manual, processor run logs, and an interview, the laboratory failed to document performance of required charcoal cartridge filter replacement maintenance according to the manufacturer's instructions in calendar years 2017 and 2018. Findings include: 1. Review of the laboratory's monthly Sakura Tissue-Tek VIP instrument maintenance logs revealed activated carbon charcoal cartridge filter

	replacement listed as: "perform quarterly". During the log review, the inspector noted no charcoal filter replacement was documented in calendar year 2017 and one (1) charcoal filter replacement was documented in 2018 (on 5/15/18). Additional documentation of filter replacement in calendar years 2017 and 2018 was requested. No records were available. 2. Review of the Sakura Tissue-Tek Operations Manual stated: "the activated carbon filter replacement should be completed on a monthly basis after every 20-25 runs". 3. Review of the monthly processor logs revealed one hundred eighty-eight (188) runs in 2017 and one hundred eighty-five (185) runs in calendar year 2018. The inspector noted one charcoal filter replacement was documented in the twenty-four (24) months reviewed while three hundred seventy-three (373) runs were processed. 4. In an exit interview with the practice manager and primary lab technician at 4:30 PM, the above listed findings were confirmed.