Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0675231	06/01/2023
Name of Provider or Supplier	**Street Address, City, State**	
Evms Department Of Dermatology-Lewis Hall	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 Department of Dermatology-Lewis Hall on June 1, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiency cited is as follows:
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 a review of procedures, maintenance logs, and interviews, the laboratory failed to document performance of daily, bi-weekly, weekly, and monthly histopathology equipment maintenance according to the manufacturer's instructions during eighteen (18) of twenty-three (23) months reviewed. Findings include: 1. Review of the laboratory's procedures revealed the following required histopathology equipment maintenance protocols. The protocols stated, "perform per manufacturer's instructions and at the end of each month the laboratory director must sign each log": Water Bath: Daily wipe down machine and remove visible paraffin from basin and exterior, log water bath temperature each day in use, weekly empty the water and disinfect surface, air dry; Tanner 1700 Embedding Station: Daily check paraffin levels and top off if necessary, wipe down working surfaces, wash metal molds. Bi-weekly remove paraffin from outer machine, empty/clean paraffin drip tray, empty/clean tissue chamber; Microtome Maintenance (Machines #2125, #2135): Daily wipe down instruments, weekly disassemble/clean knife holder, monthly oil machine; Oven: clean instrument monthly; Staining/Grossing Hood Station: Daily disinfect grossing instruments, remove all specimen containers to biohazard storage bin. Weekly rotate xylenes and 100% ethanol, change water, disinfect/refill formalin containers, Bi-

	Weekly change bluing, 70% and 95% ethanol, hematoxylin, and eosin. Monthly clean staining rack and replace pads in fume hood. Change hematoxylin filter as needed; Tissue Tek VIP Processor #52150289: Daily drain, wipe out retort, lid, and gasket, run the cleaning cycle, change fume control water reservoir, record retort temperature daily. Weekly rotate all reagents, run a warm flush using reservoir #1 and #2 filled with hot tap water, clean retort with 70% ethanol. Monthly replace charcoal filter, clean processing chamber lid, check gasket and bottle insertion O-rings, exchange all reagents. Preventative Maintenance is to be completed in September annually. 2. Review of the laboratory's available histopathology instrument maintenance logs for a 23 month review timeframe (July 2021 through May 2023) revealed no daily, bi-weekly, weekly, and monthly maintenance records for instrument/tasks outlined above from 7/1/21 through 12/31/22. The inspector requested to review documentation of the maintenance tasks for the 18 months of July-December 2021 and January - December 2022. The histotech provided records for January - May 2023. No additional maintenance logs were available for review. 3. An interview with the laboratory director, two histotechs, and practice manager on 6/2/23 at approximately 1:45 PM confirmed the above findings.