Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0229697	04/21/2022
Name of Provider or Supplier	**Street Address, City, State**	
Pariser Dermatology Specialists Ltd	6160 Kempsville Circle - Suite 200a, 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 Pariser Dermatology Specialists LTD (Norfolk) on April 20-21, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The inspector noted that the laboratory performs SARS-CoV-2 (COVID-19) testing and was in compliance with the applicable COVID-19 reporting requirements. 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 the Clinical Laboratory Improvement Amendments Application for Certification form (CLIA 116), tour, review of equipment user manual, maintenance logs, lack of documentation, and interviews, the laboratory failed to document daily and weekly histopathology preventative maintenance procedures according to the Leica CV5030 manufacturer's instructions for fourteen (14) of 14 months reviewed (February 2021 to the date of the survey on April 21, 2022). Findings include: 1. Review of the CMS 116 form on 4/20/22 revealed that the laboratory indicated two new histopathology laboratory equipment which included a Leica CV5030 Robotic Coverslipper (Serial Number RS485). 2. During a facility tour (pathology section) on 4/21/22 at approximately 11:00 AM, the inspector noted the Leica CV5030 Robotic Coverslipper, outlined above, in use in the histopathology specimen processing lab room. The inspector inquired regarding the date the laboratory installed the CV5030 equipment. The laboratory manager provided the installation date of February 2021. 3. Review of the Leica CV5030 user manual revealed the following preventative maintenance instructions: Daily - remove

	adhesive residue and broken glass, check plastic container/refill with 5ml solvent, check level of glass vial in dispenser rest/park position, fill loading bath with solvent, prime dispenser needle with coverslip mountant and check flow, inspect cover slip catch tray; Weekly - replace all the solvent in the loading bath, rinse the dispenser group with solvent, check the brush of dispenser needle cleaner, replace any dirty/hard brushes; As Necessary (PRN) - fill coverslipping mounting bottle, replace carbon filter (no later than after every three months), check transfer station and clean as necessary (transfer arm, discharge chute) 4. Review of the laboratory's histopathology instrument maintenance logs revealed no documentation for the maintenance outlined above. The inspector requested to review documentation of the daily, weekly, and PRN tasks outlined by the manufacturer for the Leica CV5030 for the 14 months since installation in February 2021. No documentation was available for review. 5. An exit interview with the Clinical Operations Manger, Pathology Lab Manager, and Moh's Tech, on 4/21/22 at approximately 12:30 PM, the above listed findings were confirmed.