Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0229697	11/06/2019
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 on November 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:
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 tour, review of microtome user manual, instrument maintenance logs, and interviews, the laboratory failed to document annual preventative maintenance according to the manufacturer's instructions for two (2) of three (3) tissue section processors during the twenty-four (24) months reviewed. Findings include: 1. During a facility tour at approximately 11:00 AM, the inspector noted 3 Sakura AccuCut SRM 200 Rotary Microtome instruments in use in the histopathology specimen processing lab room (instruments were tagged/identified as A, B, and C). 2. Review of the Sakura Microtome user manuals revealed "Care of the Instrument" maintenance checklist instructions that stated: "Have the instrument inspected yearly by a qualified service technician authorized by Sakura Finetek as preventative maintenance (PM)". 3. Review of the laboratory's Sakura instrument maintenance logs for microtome A, B, and C revealed: Microtome A installation service was performed on 02/25/19. The inspector requested to review documentation of a yearly PM for microtome "B"-serial number (SN) 03597 and "C"- SN 14290194 for the timeframe of November 2017 to 11/6/19. No records were available. The laboratory manager stated, at approximately 12:30 PM, "we do not have yearly PM's scheduled for the instrumentation but we do call for service on an as needed basis". 4. In an exit interview with the laboratory manager

	and practice manager, at approximately 2:00 PM, the above listed findings were confirmed. B. Based on a tour, review of users manual, instrument maintenance logs, and interviews, the laboratory failed to document slide dryer's cleaning and temperature maintenance checks according to the manufacturer's maintenance instructions in the twenty-four (24) months reviewed. Findings include: 1. During a facility tour at approximately 11:00 AM, the inspector noted one (1) Quincy Lab Model GC Series Lab Oven in use for patient tissue slide drying in the histopathology specimen processing room. 2. Review of the Model GC Series Lab Oven users guide revealed a highlighted "Periodic Oven Maintenance" section on page 4 that stated: "Operation safety requires periodic cleaning and chamber temperature accuracy verification. Periodically check/clean the rear air intake vents. Keep the intake and exit ports clear of obstruction, dust, and dirt. Once a year, check the oven chamber temperature against a known accurate temperature measurement device. Calibrate the control as necessary". 3. Review of the laboratory's instrument maintenance logs revealed no record of the Model GC Series Oven cleaning or temperature verification maintenance outlined above (timeframe of review: November 2017 to 11/6/19). The inspector requested to review the maintenance documentation. No records were available. The laboratory manager stated, at approximately 1:00 PM, "We have not performed the maintenance. We use the unit to dry slides prior to immunohistochemistry (IHC) staining. We were not instructed to do those maintenance procedures when the unit was installed". 4. In an exit interview with the laboratory manager and practice manager, at approximately 2:00 PM, the above listed findings were confirmed.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on a tour, review of maintenance logs, and interviews, the laboratory failed to establish maintenance protocols for three (3) of five (5) microscopes utilized for histopathology patient testing during the twenty-four (24) months reviewed. Findings include: 1. During a facility tour at approximately 11:00 AM, the inspector noted the following three (3) microscopes in the histopathology specimen processing area: Nikon model E600 Serial Number (SN) 117796, Olympus Model BX43 SN 4H41210, Nikon YS2-T Serial# 148792. The inspector noted the following 2 microscopes in the nurse station work areas: Accuscope EXC 120 Series SN 1209016, Accuscope EXC 120 Series SN 070039. 2. A review of the laboratory's equipment maintenance logs (timeframe: November 2017 to date of inspection) revealed no record of preventative maintenance for the Nikon E600 SN 117796, Olympus BX43 SN 4H41210, or Nikon YS2-T SN 148792. The inspector requested to review the written maintenance protocols for the 3 microscopes utilized for histopathology patient testing listed above. No documentation was available for review. The laboratory manager stated, at approximately 12:00 PM, "We have protocols for Tidewater Medical Sales and Service to come in to perform yearly maintenance checks on the microscopes but they

	checked and PM'd only the Accuscope microscopes. We have not added the other microscopes to that annual PM protocol". 3. In an exit interview with the laboratory manager and practice manager, at approximately 2:00 PM, the above listed findings were confirmed.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures and an interview, the laboratory director (LD) failed to ensure that a quality assurance (QA) policy for the histopathology test procedures performed in the specimen processing room was established and maintained during the twenty-four (24) months reviewed. Findings include: 1. Review of the laboratory's policy and procedure manuals revealed no written and approved QA policy to include preanalytical, analytical, and post analytical quality measures for the histopathology specimen processing testing room during the timeframe of November 2017 to 11/6/19. The inspector inquired of laboratory QA protocols to correct problems such as missed required histopathology instrument/equipment maintenance utilized in the specimen processing room. The laboratory manager stated "We do not have a written QA policy. We do keep a corrective action log and address concerns as they arise". 2. In an exit interview with the laboratory manager and practice manager, at approximately 2:00 PM, the above listed findings were confirmed.