Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0893619	10/10/2018
Name of Provider or Supplier	**Street Address, City, State**	
Pariser Dermatology Specialists	11842 Rock Landing Rd, Ste 120, Newport News, 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 on October 10, 2018 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:
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on a laboratory tour, review of the policy manual, and interviews, the laboratory failed to follow their written policy for labeling MOHS slides using patient accession number, patient last and first name, date, and layer/specimen number for four (4) of (4) cases observed on the date of the survey, October 10, 2018. Findings include: 1. During a laboratory tour, at approximately 1:00 PM on 10/10/18, the inspector observed 4 patient MOHS cases with slides in the testing processing area. The inspector noted that for each of the 4 cases, the slides were labeled with one patient identifier (patient last name), the number 10/10, and a layer alphabet. 2. Review of the policy manual revealed a Slide Preparation, Completion, and Storage Procedure, Revision Date 2/25/17, that stated : "With Tissue Tek slide marker, write patient's last name, first initial, date, tissue layer, and section number on each slide". The inspector noted a procedure addendum for labeling and accessioning of MOHS slides that stated "Slides are labeled with Zebra EMR printed label that will contain the patient accession number, patient last and first name, date, and each layer /specimen number." 3. The inspector asked the primary TP and operations manager, at

	approximately 2:00 PM, to describe the process of adding the zebra printer labels to the patient slides. The primary TP stated: "We do not have a zebra printer here at Newport News. We have not been following the policy of labeling with accession number and patient last and first name onsite. It is not until we print the labels at our main lab in Norfolk that we add the printed label with additional identifiers to the hand written labels before the slides are put in storage". 4. In an interview with the operations manager and lead TP at approximately 3:30 PM, it was confirmed that the laboratory failed to follow their written policy for labeling MOHS slides using two (2) positive unique identifiers (patient accession number, patient first and last name) at the time of tissue sample receipt onsite and through the testing/resulting as outlined above.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on a laboratory tour, review of policies, and interviews, the laboratory failed to label the in use Hematoxylin and Eosin (H & E) reagents, at total of sixteen (16) containers, with appropriate identification on the date of the inspection, October 10, 2018. Findings include: 1. During a laboratory tour at approximately 1:00 PM on 10 /10/18, the inspector noted that the sixteen (16) H & E staining containers in use for staining slides for MOHS testing were not labeled with content name, lot number, open date or an expiration date. The inspector asked the primary testing personnel (TP) to describe the laboratory guidelines used to determine the staining order by hand staining. The TP stated: "Our containers are not labeled now because the label's adhesive fell off, but I am ordering new labels". 2. Review of the policy and procedure manual revealed a Frozen Section Staining policy that included instructions: "all slides are stained in this order by hand staining: 95% Alcohol for 2 minutes, Water (dip until clear), Hematoxlyin for 2 minutes, Water, Bluing Solution, Water, Water, 95 % Alcohol, Eosin, 95 % Alcohol, 95 % Alcohol, 95 % Alcohol, 100 % Alcohol, 100 % Alcohol, 100 % Alcohol, Citrisolve. Staining set up is in the weekly duties procedure". Review of the weekly duties procedure revealed a Quality Assurance (QA) statement: "Discard reagents that are unlabeled or those whose expiration date has passed". 3. During an interview with the primary TP and practice manager at approximately 3:30 PM, it was confirmed that, on the date of the survey, the laboratory failed to label 16 of 16 H & E staining reagents with the required identification of reagent name and expiration date.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

	This STANDARD is not met as evidenced by: Based on a laboratory tour, review of policy and procedure manual, and interviews, the laboratory failed to ensure that their Potassium Hydroxide (KOH) 10% and fungal stain reagent, stored in the microscopy area, were within the manufacturer's stated expiration dates for two (2) lot numbers of reagents. Findings include: 1. During a laboratory tour of the microscopy area at approximately 1:15 PM on 10/10/18, the inspector noted the following 2 expired reagents stored beside the Olympus CH microscope: One (1) bottle of HealthLink Potassium Hydroxide (KOH) 10%, Lot Number 1425304, with manufacturer's printed expiration date of 7/2017; 1 bottle of HealthLink Fungal Black E Stain, Lot Number 400308, with manufacturer's printed expiration date of 9/10/2017. The laboratory inspector asked if the expired KOH and fungal stain reagents were being used for patient testing and the operations manager stated: "Yes, they are being used but we will reorder today". 2. Review of the laboratory's policy and procedure manual revealed a Potassium Hydroxide (KOH) Examination procedure that included a Reagents Storage, Use, and Handling protocol that stated: "Do not use the KOH 10% and KOH with Chlorazol Black E reagents after the expiration date". 3. During an interview with the primary testing personnel and operations manager at approximately 3:30 PM, it was confirmed that the laboratory failed to ensure that the 2 KOH Examination reagents, listed above, were not used beyond the expiration dates.