Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0918172	08/23/2018
Name of Provider or Supplier	**Street Address, City, State**	
Pariser Dermatology Specialists, Ltd	207 Bulifants Blvd - Suite C, Williamsburg, 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-Williamsburg on August 23, 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 laboratory's policy manual, patient test logs, and interviews, the laboratory failed to follow their written policy for labeling MOHS slides using patient accession number, patient name, and layer/specimen number for thirteen (13) of thirteen (13) months reviewed while processing one thousand one hundred (1,100) patient cases. Findings include: 1. During a laboratory tour, the inspector observed three (3) patient MOHS slides in the testing processing area. The inspector noted that each slide was labeled with one patient identifier. The inspector asked the primary testing personnel (TP) to describe the process of labeling the MOHS slides. The testing personnel stated: "We write an accession or case number and each layer number on our slides." 2. Review of the policy manual revealed a procedure for labeling and accessioning of MOHS slides that stated: "Slides are labeled in pencil on the frosted end of the slide and will contain the patient accession number, patient name, and each layer/specimen number". 3. Review of the patient test logs from July 2017 to the date of the survey on August 23, 2018 revealed one thousand one hundred (1,100) MOHS cases listed by patient case number. The inspector requested the following five (5) random case numbers to be pulled for

	review: Case slide 235, processed on 10/26/17, did not have a patient name on the slides. Case slides WB18-008, WB18-009, WB18-010, WB18-011, processed on 1/18 /18, did not have patient names on the slides. The inspector and the TP reviewed the laboratory's written procedure for labeling of slides at approximately 12:00 PM, and the primary TP stated: "We have never written the patient's name on our slides. The policy does state that we will write the name but we have not followed that policy". 4. In an interview with the operations manager at approximately 12:30 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 and patient name) during the thirteen (13) of thirteen (13) months reviewed while processing one thousand one hundred (1,100) patient cases.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of the policy manual, manufacturer's Dermatophyte Test Media (DTM) package insert, DTM patient logs, and an interview, the laboratory failed to follow the manufacturer's instructions for incubation time for three (3) of twenty (20) random patient tests reviewed from March 1, 2018 to August 23, 2018. Findings include: 1. Review of the laboratory's Dermatology Procedure Manual revealed a Fungal Culture policy that outlined that the laboratory utilizes Accuderm's ACU-DTM Dermatophyte Test Medium to detect dermatophytes from patient cutaneous sources. The policy stated: "The culture must be interpreted by a provider within 10-14 days of inoculation. Any culture that has not been interpreted within 14 days must be repeated". 2. The Accuderm's manufacturer's package insert defined the patient incubation period of up to fourteen (14) days and instructions to disregard any color change in the medium after the 14 days of incubation. The package insert instructions stated: "Reading should be made within fourteen days. Color interpretation of the test is questionable after fourteen (14) days due to the possibility of false positives". 3. The inspector selected twenty (20) random patient case numbers from the DTM patient logs from the timeframe of March 1, 2018 to the day of the survey on August 23, 2018. Review of the selected patient DTM culture results revealed the following case number entries having incubation periods exceeding fourteen (14) days: Case number 5074000 on 03/30/18 incubated twenty-four (24) days; Case number 1906090 on 06/13/18 incubated fifteen (15) days; Case number 2013990 on 06/28/18 incubated nineteen (19) days; a total of three (3) of the twenty (20) patient results were recorded outside of the manufacturer's recommended incubation time. The inspector requested to review the repeat cultures for the case numbers listed above. No repeat culture results were available for review. 4. In an interview with the operation manager at approximately 12:30 PM , it was confirmed that the laboratory did not follow the manufacturer instructions for DTM incubation for the three (3) of twenty (20) patent case numbers as outlined above.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409

	The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, and interview, the technical consultant failed to perform annual Potassium Hydroxide (KOH) competency assessments for six (6) of six (6) testing personnel in 2017 (Cross reference D6054).
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, and an interview, the technical consultant (TC) failed to perform annual Potassium Hydroxide (KOH) competency assessments for six (6) of six (6) testing personnel in 2017. **REPEAT DEFICIENCY Findings include: 1. Review of the CMS Form 209 revealed that there are six (6) testing personnel performing KOH patient testing and that the lab director (LD) performs the duties of TC. (See Personnel Code Sheet.) 2. Review of the laboratory personnel files revealed no record of KOH annual competency assessments or split sample documentation in calendar year 2017 for: Testing personnel A, Testing personnel B, Testing personnel C, Testing personnel D, Testing personnel E, Testing personnel F. The inspector requested to review the 2017 annual competency documentation. The documentation was not available for review. 3. In an interview with the operations manager at approximately 12:30 PM, it was confirmed that the laboratory failed to document KOH competency assessments for the six (6) testing personnel outlined above in calendar year 2017.