Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2022169	03/06/2018
Name of Provider or Supplier	**Street Address, City, State**	
Pariser Dermatology Specialists	3907 Bridge Road, Suite 200, Suffolk, 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 Specialist (Suffolk) on March 6, 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:
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of the procedure manual and an interview, the laboratory failed to verify the accuracy of Potassium Hydroxide (KOH) and dermatological Wet Preparations (Preps) microscopic examinations in calendar years 2016 and 2017. Findings include 1. The review of the procedure manual revealed that the laboratory performs dermatological Wet Preps and KOH microscopic slide examinations, which are categorized as moderately complex and non-regulated tests. The inspector requested to review the documentation of twice a year accuracy checks for the aforementioned tests in 2016 and 2017. The documentation was not available for review. 2. An interview with the laboratory director at approximately 3:45 PM confirmed that the laboratory failed to verify the accuracy of dermatological Wet Preps and KOH microscopic examination for 2016 and 2017.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

	This STANDARD is not met as evidenced by: Based on the review of the CMS Application for Certification Form (CLIA 116), CMS Laboratory Personnel Form (CLIA 209), policy and procedure manual and interview, the laboratory director failed to document approval and date of review for the written policies and procedures at the date of survey on March 6, 2018. Findings include: 1. Review of the CLIA 116 and CLIA 209 forms revealed that there was a change in laboratory director. The inspector reviewed a signed document from the previous laboratory director assigning laboratory directorship to the current laboratory director for the Mohs histological test system on July 17, 2017. 2. Review of the policy and procedure manual for the Mohs histological test system revealed no documentation of approval and date of review of the written policies and procedures by the current laboratory director. 3. An interview with the laboratory director at approximately 3:45 PM confirmed that the current laboratory director failed to review and approve the policy/procedure manual.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of Dermatophyte Test Media (DTM) quality control (QC) records, patient test logs, and an interview, the laboratory failed to document before or concurrent with use the ability of the DTM to grow, inhibit growth and produce the expected biochemical response for the twelve (12) of twenty-four (24) months reviewed. Findings include: 1. Review of DTM QC records revealed there was no QC documentation from January 1, 2016 through December 31, 2016. The inspector requested to review DTM QC records for 2016. The records were not available for review. 2. Review of the patient DTM test logs revealed sixty-eight (68) patient cultures reported from January 1, 2016 through December 31, 2016. 3. An interview laboratory director at approximately 3:45 PM confirmed the laboratory failed to document DTM QC from January 1, 2016 through December 31, 2016.