

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D0229697	<b>(X3) Date Survey Completed</b> 01/23/2018
<b>Name of Provider or Supplier</b> Pariser Dermatology Specialists Ltd	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA recertification survey was conducted at Pariser Dermatology Specialists on January 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:
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p> <p>A. 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 2016 and 2017. Findings include 1. 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 for 2016 and 2017. The documentation was not available for review. 2. An interview with main testing personnel at approximately 3:30 PM confirmed that the laboratory failed to verify the accuracy of dermatological Wet Preps and KOH microscopic examination for 2016 and 2017. B. Based on a review of the procedure manual and an interview, the laboratory failed to verify the accuracy of Dermatophyte Test Medium (DTM) cultures in 2016. Findings include: 1. The laboratory performs DTM cultures, which are categorized as moderately complex and non-regulated tests. The inspector requested to review the documentation of twice a year accuracy checks for 2016. The documentation was not available for review. 2. An interview with main testing personnel at approximately 3:30 PM confirmed that the laboratory failed to verify the accuracy of DTM cultures in 2016.</p>

**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 record review, patient test logs, and an interview, the laboratory failed to document quality control for DTM (dermatophyte) test medium for twenty-one (21) of twenty-four (24) months reviewed. Findings include: 1. Review of quality control (QC) records for DTM cultures revealed QC documented from October 11, 2017 to the date of survey, January 23, 2018. The inspector requested to review the QC documentation for DTM cultures for January 2016 up to October 11, 2017. No other records were available for review. 2. Review of patient DTM test logs revealed four hundred eighty-one (481) patient cultures reported from January 2016 to October 11, 2017. 3. An interview with primary testing personnel at approximately 3:30 PM confirmed that the laboratory failed to document DTM QC for twenty-one (21) of twenty-four (24) months reviewed.