

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0931785	(X3) Date Survey Completed 06/29/2023
Name of Provider or Supplier Pariser Dermatology Specialists Ltd	Street Address, City, State 1248 Perimeter Parkway-Suite 482, Virginia Beach, 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	<p>An announced CLIA recertification survey was conducted at Pariser Dermatology Specialists LTD (Virginia Beach) on June 28, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The survey also included a follow up interview with the practice manager on 6/29/23. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows and includes the Condition under 42 CFR part 493 CLIA Regulation: D5400 -42 CFR. 493.1250 Analytic Systems.</p>
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on a review of manufacturer's package insert, procedures, quality control (QC) logs, patient logs, lack of documentation, and interviews, the laboratory: 1. failed to follow manufacturer's dermatophyte test medium (DTM) QC instructions on four (4) of 4 QC log sheets during a timeframe of November 2, 2022 to the date of the inspection on June 28, 2023. Cross Reference D5411; 2. failed to retain documentation of performance/verification of a positive and negative control of DTM media for sixteen of twenty-three months reviewed while reporting one hundred twenty-four patient DTM culture results (review timeframe: 7/8/21 through the dated of the inspection on June 28, 2023). Cross Reference D 5477.</p>

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 manufacturer's package insert, quality control (QC) logs, lack of documentation, and interviews, the laboratory failed to follow manufacturer's dermatophyte test medium (DTM) QC instructions to retain lot number labels on four (4) of 4 QC log sheets during a timeframe of November 3, 2022 to the date of the inspection on June 28, 2023. Findings include: 1. Review of Acu-Derm DTM manufacturer's package insert revealed QC instructions as: "The user is required to perform a minimum of a positive and negative control on each new lot or batch purchased. Maintain a log of the microorganism ATCC QC labels with lot number. Retain the log for inspection purposes." 2. During a review of QC logs for timeframe from 7/8/21 to the date of the inspection on 6/28/23, the inspector noted 4 QC log sheet records: 11/03/22 - two log sheets for DTM lot numbers 1452-0122 and 164-052; 03/07/23 - two log sheets for DTM lot numbers 1486-0123 and 593-932. The inspector noted that the 4 log sheets outlined above did not include ATCC lot number labels nor denotation of the lot numbers utilized for the Trichophyton mentagrophyte (positive QC), E.coli (negative QC), Aspergillus niger, or Candida albicans microorganisms. 3. The inspector inquired regarding the ATCC QC lot numbers utilized for QC verification on the log sheets dated on 11/3/22 and 3/7/23. The practice manager stated on 6/28/23 at approximately 12:30 PM, "I have looked back and found one invoice for one order of the DTM ATCC QC. I can check with our supplier, McKesson, if they can verify the ATCC lot numbers for the negative and positive controls. I can check with them also for the records of QC materials and lot numbers ordered/received prior. I do not have that information today" The inspector noted the provided March 2023 invoice was dated as QC kit ordered on 3/1/23. 4. During a follow up interview with the practice manager on 6/29/23 at approximately 9 AM, the manager stated, "I have not been able to get QC lot numbers from McKesson." The interview with the practice manager on 6/29/23 at approximately 9 AM confirmed the above findings.

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 a review of procedures, tour, manufacturer's package insert, quality control (QC) logs, patient logs, lack of documentation, and interviews, the laboratory failed to

retain documentation of verification of a positive and negative control of their DTM media during sixteen (16) of twenty-three (23) months reviewed while reporting one hundred twenty-four (124) patient DTM culture results (review timeframe: July 8, 2021 through the dated of the inspection on June 28, 2023). Findings include: 1. Review of procedures revealed an Acu-Derm DTM culture procedure that outlined, "Check each batch of media for sterility and follow manufacturer's QC guidelines." 2. During a tour of the DTM testing area on 6/28/23 at approximately 11 AM, the inspector noted one opened box of Acu-Derm DTM media stored in the refrigerator for use (lot number 1486-0123 box of twenty-four vials, ten remaining). Review of the enclosed Acu-Derm DTM manufacturer's package insert revealed QC instructions as, "The user is required to perform a minimum of a positive and negative control on each new lot or batch purchased." 3. A review of DTM QC logs (7/8/21 - 6/28/23) revealed the following lapses in 2021 and 2022 QC documentation: July 2021 through December 2021 - six months without QC recorded in calendar year 2021; January 2022 through October 2022 - ten months without QC recorded in calendar year 2022; a 16 month timeframe with no record verification of a positive and negative control for DTM culture media. The inspector requested to review DTM QC logs for verification of positive/negative reactions for the 16 months outlined above. The practice manager stated on 6/28/23 at approximately 12:30 PM, "I was not here during that timeframe and cannot verify where the records would be located." No additional DTM QC was available for review. 4. Review of patient DTM test logs revealed 124 patient DTM culture results were reported during the 16 month QC lapse outlined above. 5. An interview with the office practice manager on 6/28/23 at approximately 2:30 PM confirmed the above findings