

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2072133	(X3) Date Survey Completed 02/12/2019
Name of Provider or Supplier Pariser Dermatology Specialists, Ltd	Street Address, City, State 510 Independence Parkway Suite 600, Chesapeake, 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, LTD on February 12, 2019 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	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE 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: Based on a review of procedures and policies, proficiency testing (PT) logs, and an interview, the laboratory failed to perform accuracy evaluations twice a year for fungal culture testing in calendar year 2017. Findings include: 1. Review of the laboratory's procedure manual revealed a dermatophyte culture PT policy that stated, "proficiency will be completed twice a year for providers using Acu-Derm test kits and DTM ATCC control samples following our procedure for fungal cultures". 2. Review of the laboratory's 2017 and 2018 Proficiency Testing Logs revealed one (1) DTM PT evaluation was documented during calendar year 2017 (dated 4/24/17). The inspector requested to review additional PT documentation of DTM fungal culture accuracy evaluations in calendar year 2017. No other records were available for review. 3. In an exit interview with the operation manager at approximately 3:30 PM, the above findings were confirmed.</p>
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic</p>

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.

This CONDITION is not met as evidenced by:

Based on a review of the policy manual, ACU-DTM Dermatophyte Test Medium package insert, patient logs, problem logs, and an interview, the laboratory failed to:

1. follow the manufacturer's instructions for culture incubation time for seven (7) of eighteen (18) randomly selected patient fungal culture results in calendar years 2017 and 2018 (*REPEAT DEFICIENCY). See D 5411.
2. follow their corrective action policy to repeat patient fungal cultures when incubation time exceeds fourteen (14) days for one (1) of 7 patient culture results reviewed between January 5, 2017 to February 28, 2017 and six (6) of eleven (11) patient results reviewed from March 1, 2018 to May 1, 2018. See D 5779.

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 package insert, patient logs, and an interview, the laboratory failed to follow the manufacturer's instructions for culture incubation time for one (1) of seven (7) patient culture results reviewed between January 5, 2017 to February 28, 2017 and six (6) of eleven (11) patient results reviewed from March 1, 2018 to May 1, 2018. *REPEAT DEFICIENCY 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 eighteen (18) random patient case numbers from the 2017 and 2018 DTM patient logs during the timeframes of 1/5/17 to 2/28/17 and 3/1/18 to 5/1/18 for review. The review of the randomly selected patient DTM culture results revealed the following case number entries having incubation periods exceeding fourteen (14) days: Case number 0231440 on 01/23/17 incubated twenty-four (24) days; Case number 2862730 on 02/01/18 incubated forty-five (45) days; Case number 2038460 on 02/05/18 incubated fifteen (15) days; Case number 2876080 on 03/09/18 incubated thirty-four (34) days; Case number 2880090 on 03/15/18 incubated eighteen (18) days; Case number 1911900 on 03/16/18 incubated seventeen (17) days; Case number 2882550 on 03/23/18 incubated twenty

(20) days; a total of 7 of 18 patient results were recorded outside of the manufacturer's recommended incubation time. 4. In an exit interview with the operation manager at approximately 3:30 PM, the above findings were confirmed.

D5779

CORRECTIVE ACTIONS

CFR(s): 493.1282(a)

Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.

This STANDARD is not met as evidenced by:

Based on a review of the policy manual, patient logs, problem logs, and an interview, the laboratory failed to follow their corrective action policy to repeat patient fungal cultures when incubation time exceeds fourteen (14) days for one (1) of seven (7) patient culture results reviewed between January 5, 2017 to February 28, 2017 and six (6) of eleven (11) patient results reviewed from March 1, 2018 to May 1, 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 inspector selected eighteen (18) random patient case numbers from the 2017 and 2018 DTM patient logs during the timeframes of 1/5/17 to 2/28/17 and 3/1/18 to 5/1/18 for review. The review of the randomly selected patient DTM culture results revealed the following case number entries having incubation periods exceeding fourteen (14) days: Case number 0231440 on 01/23/17 incubated twenty-four (24) days; Case number 2862730 on 02/01/18 incubated forty-five (45) days; Case number 2038460 on 02/05/18 incubated fifteen (15) days; Case number 2876080 on 03/09/18 incubated thirty-four (34) days; Case number 2880090 on 03/15/18 incubated eighteen (18) days; Case number 1911900 on 03/16/18 incubated seventeen (17) days; Case number 2882550 on 03/23/18 incubated twenty (20) days; a total of 7 of 18 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. 3. Review of 2017 and 2018 patient problem logs revealed no corrective action for the 7 case numbers outlined above. 4. In an exit interview with the operation manager at approximately 3:30 PM, the above findings were confirmed.