

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2163278	(X3) Date Survey Completed 12/18/2024
Name of Provider or Supplier Masri-Fridling Dermatology Group	Street Address, City, State 8605 Westwood Center Drive, Suite 309, Vienna, 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 Masri-Fridling Dermatology Group on December 18, 2024 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows and includes the Conditions 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 the laboratory's policy and procedure manual, manufacturer's package insert, patient logs, plan of correction (dated 02/13/2023), lack of documentation and an interview, the laboratory failed to follow their plan of correction and manufacturer's instructions for culture incubation time for patient fungal cultures resulted between between March 2023 and December 18, 2024. See D5411.</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed</p>

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:

****REPEAT DEFICIENCY**** Based on a review of the laboratory's policy and procedure manual, manufacturer's package insert, patient logs, plan of correction (dated 02/13/2023), lack of documentation and an interview, the laboratory failed to follow their plan of correction and manufacturer's instructions for culture incubation time for five (5) of twenty-eight (28) patient fungal culture results reviewed between March 2023 to the date of the survey on December 18, 2024. The findings include: 1. During a tour of the laboratory on December 18, 2024 at 9:00 AM, the surveyor noted the laboratory utilizes Accuderm AcuDTM Dermatophyte test Medium for the detection of dermatophytes from patient samples. 2. Review of the laboratory's procedure manual revealed a procedure, "Fungal Culture/Dermatophyte Test Medium (DTM)". The procedure stated "Test Procedure...3. Examine the culture at the following times: 2 weeks for the growth characteristics reported in Reading Results below." 3. Review of the Accuderm's manufacturer's package insert instructions revealed a statement, "Reading should be made within fourteen days. Interpretation of the test is questionable after fourteen days due to the possibility of false positives". 4. Review of the laboratory's DTM log from March 2023 to the date of the survey on December 18, 2024 revealed the following patient numbers/cultures having incubation periods outside of 14 days: Patient number 15840731 on 08/15/2023 incubated 16 days; Patient number 20140961 on 08/16/2023 incubated 15 days; Patient number 18614957 on 08/28/2023 incubated 16 days; Patient number 17954518 on 08/29/2023 incubated 15 days; Patient number 15935803 on 04/30/2024 incubated 15 days. A total of 5 patient results were recorded outside of the manufacturer's recommended incubation time of 2 weeks. 5. Review of the laboratory's plan of correction (dated 02/13/2023) revealed the following statements, "DTM cultures will be read at exactly 14 days. Alerts will be set in an electronic calendar attached to the EHR that will generate reminder alerts to do the final reading and reporting for cultures in 2 weeks... Each quarter the lab director will review the cultures performed to ensure alerts are timely and entered correctly." The surveyor requested to review the quarterly review of cultures from February 2023 until the date of the survey on December 18, 2024. The laboratory provided no documentation for review. 6. In an interview with the Laboratory Director on December 18, 2024 at 11:00 AM, the findings were confirmed.