

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2163278	(X3) Date Survey Completed 02/08/2023
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	An announced CLIA recertification survey was conducted at Masri-Fridling Dermatology Group on February 8, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiency cited is as follows:
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 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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy and procedure manual, manufacturer's package insert, patient logs, and an interview, the laboratory failed to follow the manufacturer's instructions for culture incubation time for eight (8) of thirty (30) patient fungal culture results reviewed between June 16, 2021 to the date of the survey on February 8, 2023. Findings include: 1. During a tour of the laboratory on February 8, 2023 at approximately 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 June 16, 2021 until the date of the survey on February 8, 2023</p>

revealed the following patient numbers/cultures having incubation periods outside of 14 days: Patient number 18723789 on 07/26/2021 incubated 15 days; Patient number 15844284 on 08/10/2021 incubated 15 days; Patient number 17767164 on 09/08/2021 incubated 18 days; Patient number 16291272 on 09/15/2021 incubated 15 days; Patient number 23292448 on 03/17/2022 incubated 18 days; Patient number 15843150 on 03/22/2022 incubated 16 days; Patient number 15841070 on 07/28/2022 incubated 19 days; Patient number 17964537 on 09/21/2022 incubated 19 days. A total of 8 patient results were recorded outside of the manufacturer's recommended incubation time. 5. In an interview with the Laboratory Director on February 8, 2023 at approximately 10:45 AM, the findings were confirmed.