

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2163278	(X3) Date Survey Completed 07/17/2019
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 initial survey was conducted at Masri-Fridling Dermatology Group on July 17, 2019 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 deficiencies are 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 policy and procedure manual, manufacturer's Dermatophyte Test Media (DTM) package insert, patient DTM log and an interview with the Laboratory Director (LD), the laboratory failed to follow the manufacturer's instructions for incubation for fifteen (15) of sixteen (16) patient DTM culture reports reviewed from February 28, 2019 to June 24, 2019. Findings include: 1. During a tour of the laboratory at approximately 9:15 AM, the surveyor noted the laboratory utilized the Accuderm's ACU-DTM Dermatophyte Test Medium to detect dermatophytes from patient cutaneous sources. 2. Review of the laboratory's policy and procedure manual revealed a procedure, "Fungal Culture/Dermatophyte Test Medium (DTM)" which stated "Test Procedure 3. Examine the culture at the following times 2 and 3 weeks for the growth characteristics reported in Reading Results below." 3. The ACU-DTM manufacturer's package insert stated "Color interpretation of test is questionable after 14 days due to the possibility of false positives." 4. Review of the laboratory's DTM Log culture results from 2/28/19 to 7/17/19 (a total of 16 patients) revealed the following: 15841602-collected and incubated on 02/28/19 and read on 04/02/19 at 33</p>

days; 15839666-collected and incubated on 03/06/19 and read on 04/02/19 at 27 days; 15869963-collected and incubated on 03/14/19 and read on 05/01/19 at 48 days; 15841846-collected and incubated on 03/18/19 and read on 04/02/19 at 15 days; 15934584-collected and incubated on 03/25/19 and read on 05/01/19 at 37 days; 15931856-collected and incubated on 04/10/19 and read on 05/02/19 at 22 days; 15838455-collected and incubated on 04/23/19 and read on 05/21/19 at 28 days; 15901720-collected and incubated on 04/29/19 and read on 05/21/19 at 22 days; 16359411-collected and incubated on 04/30/19 and read on 05/21/19 at 21 days; 16333863-collected and incubated on 05/02/19 and read on 05/21/19 at 19 days; 16334900-collected and incubated on 05/28/19 and read on 06/24/19 at 27 days; 15838938-collected and incubated on 05/29/19 and read on 06/24/19 at 26 days; 15841519-collected and incubated on 06/13/19 and read on 07/08/19 at 25 days; 15932476-collected and incubated on 06/19/19 and read on 07/15/19 at 26 days; 15931856-collected and incubated on 06/24/19 and read on 07/15/19 at 21 days; 16488418-collected and incubated on 06/24/19 and read on 07/08/19 at 14 days. A total of 16 patient cultures incubated with 15 patient culture exceeding 14 day incubation time. 5. In an exit interview with the Laboratory Director at approximately 11:45 AM, the LD confirmed the findings.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on a tour, review of Dermatophyte Test Media (DTM) manufacturer's package insert, temperature log sheets, DTM patient logs, and an interview with the Laboratory Director (LD), the laboratory did not follow manufacturer's requirements for monitoring Dermatophyte Test Medium (DTM) incubation temperatures for seventeen (17) of seventeen (17) patient DTM cultures resulted from 2/28/19 to 7/17/19. Findings include: 1. During a lab tour at approximately 9:15 AM, the surveyor noted one (1) DTM patient culture incubating at room temperature. 2. Review of the Accuderm's ACU-DTM Dermatophyte Test Medium package insert for DTM cultures revealed instructions which stated: "Incubation at room temperature 20-30 degrees C (68-86 degrees F) is satisfactory for growth of most dermatophytes." 3. Review of the laboratory's temperature logs from 2/28/19 to 7/17/19 revealed no room temperature monitoring records. The surveyor requested temperature logs recording the DTM culture room temperature for the timeframe of 2/28/19 to 7/17/19. The laboratory provided no documentation for review. 4. Review of the laboratory's DTM patient log book from 2/28/19 to 7/17/19 revealed the following 17 patient DTM cultures were tested and reported: 15841602-collected and incubated on 02/28/19; 15839666-collected and incubated on 03/06/19; 15869963-collected and incubated on 03/14/19; 15841846-collected and incubated on 03/18/19; 15934584-collected and incubated on 03/25/19; 15931856-collected and incubated on 04/10/19; 15838455-collected and incubated on 04/23/19; 15901720-collected and incubated on 04/29/19; 16359411-collected and incubated on 04/30/19; 16333863-collected and incubated on 05/02/19;

16334900-collected and incubated on 05/28/19; 15838938-collected and incubated on 05/29/19; 15841519-collected and incubated on 06/13/19; 15932476-collected and incubated on 06/19/19; 15931856-collected and incubated on 06/24/19; 16488418-collected and incubated on 06/24/19; 16048195-collected and incubated on 07/08/19. 5. In an exit interview with the Laboratory Director at approximately 11:45 AM, the LD confirmed the 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 the Dermatophyte Test Media (DTM) patient log book, quality control (QC) records, DTM manufacturer's package insert instructions, and an interview with the Laboratory Director (LD), the laboratory failed to document, before or concurrent with use, the Dermatophyte Test Medium (DTM) media's ability to grow and inhibit growth from 02/28/19 to 07/17/19 while reporting seventeen (17) patient test results. Findings include: 1. Review of the DTM patient logs from 02/28/19 to 7/17/19 revealed 17 patient fungal cultures utilizing Accuderm's ACU-DTM Dermatophyte Test Medium. The surveyor requested to see documentation of the lot numbers of media used during the review timeframe. The laboratory provided documentation of one (1) lot: D-1309-0119 expiration date of 1/23/21 received on 2/19/19. 2. Review of the laboratory's QC records revealed no documentation of the fungal media's demonstration of ability to grow and inhibit growth for lot number D-1309-0119 (exp 1/23/21) utilized from 02/28/19 to 07/17/19. The surveyor requested to review the QC for the DTM media. The laboratory provided no documentation to review. 3. Review of the Accuderm's ACU-DTM Dermatophyte Test Medium manufacturer's package insert revealed quality control instructions which stated, "the end user laboratory is required to perform a minimum of a positive and negative control on each new lot or batch purchased". 4. Review of the laboratory's DTM Log culture results from 2/28/19 to 7/17/19 (a total of 17 patients) revealed the following patients were incubated using lot number D-1309-0119 exp 1/23/21 from 02/28/19 to 07/17/17. 15841602-collected and incubated on 02/28/19; 15839666-collected and incubated on 03/06/19; 15869963-collected and incubated on 03/14/19; 15841846-collected and incubated on 03/18/19; 15934584-collected and incubated on 03/25/19; 15931856-collected and incubated on 04/10/19; 15838455-collected and incubated on 04/23/19; 15901720-collected and incubated on 04/29/19; 16359411-collected and incubated on 04/30/19; 16333863-collected and incubated on 05/02/19; 16334900-collected and incubated on 05/28/19; 15838938-collected and incubated on 05/29/19; 15841519-collected and incubated on 06/13/19; 15932476-collected and incubated on 06/19/19; 15931856-collected and incubated on 06/24/19; 16488418-collected and incubated on 06/24/19; 16048195-collected and incubated on 07/08/19. A total of 17 patient cultures incubated. 5. In an exit interview with the Laboratory Director (LD) at approximately 11:45 AM, the LD confirmed the findings.