

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0695096	(X3) Date Survey Completed 06/15/2022
Name of Provider or Supplier Ferrara Dermatology Clinic	Street Address, City, State 20045 Mack Ave, Grosse Pointe Woods, MI	
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
D5006	<p>MYCOLOGY CFR(s): 493.1203</p> <p>If the laboratory provides services in the subspecialty of Mycology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1263, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: . Based on record review and interview with the Office Manager, the laboratory failed to meet the subspecialty of mycology requirements as specified in 493.1230 through 493.1256, 493.1263, and 493.1281 through 493.1299. Findings include: 1. The laboratory failed to ensure the Potassium Hydroxide (KOH) reagent did not exceed its expiration date. Refer to D5417. 2 The laboratory failed to check each lot of Dermatophyte Test Media (DTM) for the ability to support growth, sterility, and physical characteristics. Refer D5445. ***Repeat Deficiency from 5/14/2018 survey*** 3. The laboratory failed to establish a system to ensure the testing performed is the same as the test result reported. Refer to D5801B.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager (OM), the laboratory failed to ensure the Potassium Hydroxide (KOH) reagent did not exceed its expiration date for 2 (4/05/22 and 5/31/22) of 2 patients recorded on the "DTM/KOH Log</p>

Sheet". Findings include: 1. During a tour of the laboratory on 6/15/2022 at 9:16 am, the surveyor observed the laboratory's "HealthLink Potassium Hydroxide 10%" bottle with the expiration date of 1/06/2022. 2. A review of patient records revealed for 2 (4/05/22 and 5/31/22) of 2 patients recorded on the "DTM/KOH Log Sheet" had KOH testing performed since the expiration date of the KOH reagent. 3. An interview on 06/15/2022 at 9:16 am, the OM confirmed the laboratory used expired reagent to perform patient KOH testing. ***Repeat Deficiency from 5/14/2018 survey***

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 record review and interview with the Office Manager (OM), the laboratory failed to check each lot of Dermatophyte Test Media (DTM) for the ability to support growth, sterility, and the physical characteristics for 1 (lot # D-1374-0720) of 2 lots reviewed. Findings include: 1. A review of the laboratory's "DTM Quality Control Log" revealed a lack of documentation of control testing on the media for 1 (lot D-1374-0720) of 2 lots of ACU-DTM media that was put into use on 3/05/2021. 2. A review of the "DTM/KOH Log Sheet" revealed the following number of patients tested for DTM without control measures being performed: a. 8/01/2021 to 9/30/2021 - 7 patients tested b. 10/18/2021 - 12/21/2021 - 8 patients tested c. 1/10/2022 - 3/22/2022 - 5 patients tested 3. An interview on 6/15/2022 at 10:08 am, the OM confirmed the laboratory did not perform quality control measures to check new media for the ability to support growth, sterility, and physical characteristics. ***Repeat Deficiency from 5/14/2018 survey***

D5801

TEST REPORT
CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:
A. Based on record review and interview with the Office Manager (OM), the laboratory failed to include the results of testing performed for 2 (Patient #3 and #12) of 18 patient test reports reviewed. Findings include: 1. A review of patient test reports revealed for 2 of 18 patient charts reviewed, the final test report was not in the

patient's electronic medical record (EMR) as follows: a. Patient #3 - "DTM/KOH Log Sheet" revealed Potassium Hydroxide (KOH) and Dermatophyte (DTM) testing performed on 4/22/2021 b. Patient #12 - "DTM/KOH log Sheet" revealed KOH testing performed on 11/04/2021 2. When queried on 6/15/2022 at 10:21 and 10:30 am, the OM was unable to provide the surveyor test results in the EMR system. 3. An interview on 6/15/2022 at 10:21 and 10:30 am, the OM confirmed the testing was performed and documented on the log sheets and not entered into the patient's EMR. ***Repeat Deficiency from 5/14/2018 survey*** B. Based on document review and interview with the Office Manager (OM), the laboratory failed to established a system to ensure the testing performed is the same as the test reported for 1 (Patient #15) of 18 patient charts reviewed. Findings include: 1. Record review revealed for 1 (Patient #15) of 18 patient charts reviewed, the testing performed on the "DTM/KOH Log Sheet" and that reported in the electronic medical record did not match as follows: Patient #15 a. Testing on "DTM/KOH Log Sheet" - scabies performed and documented for 2/01/2022 b. Patient EMR report - KOH prep performed and resulted in EMR on 2/01/2022 2. An interview on 6/15/2022 at 10:38 am, the OM confirmed the results in the EMR system do not match those recorded on the "DTM/KOH Log Sheet".