

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D0695096	<b>(X3) Date Survey Completed</b>  05/14/2018
<b>Name of Provider or Supplier</b>  Ferrara Dermatology Clinic	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by:                      . Based on record review and interview, the laboratory failed to retain 1) the "DTM Test Specimens" logsheets for the quality control and 2) the manufacturer's certificate of analysis for each lot number, shipment, or batch of DTM and 3) the patient logsheets for the potassium hydroxide (KOH) and dermatophyte test medium (DTM) testing for two years. Findings include: 1. On May 14, 2018 at approximately 10:10 AM, record review of the DTM quality control revealed the laboratory did not retain the "DTM Test Specimens" logsheets for 13 (May 2016 to February 2017 and March to May 2018) of 24 months reviewed. 2. On May 14, 2018 at approximately 10:10 AM, record review of the DTM media quality control logs revealed the laboratory did not retain the certificate of analysis for each lot number, shipment, or batch of DTM media for 24 (May 2016 to May 2018) of 24 months reviewed. 3. On May 14, 2018 at approximately 11:00 AM, record review of the patient logsheets for the KOH and DTM testing revealed the laboratory did not retain the logsheets for 18 (May 2016 to December 2017) of 24 months reviewed. 4. During the interview on May 14, 2018 at approximately 10:10 and 11:00 AM, an office staff member confirmed the DTM quality control logs, DTM certificate of analysis paperwork, and the KOH and DTM logsheets were not retained for two years.</p>
<b>D5006</b>	<p><b>MYCOLOGY</b> CFR(s): 493.1203</p> <p>If the laboratory provides services in the subspecialty of Mycology, the laboratory</p>

must meet the requirements specified in 493.1230 through 493.1256, 493.1263, and 493.1281 through 493.1299.

This CONDITION is not met as evidenced by:

Based on document review and interview, 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 written competency policies contained the six requirements from subpart M and was implemented. Refer to D5209. 2. The laboratory failed to have an electronic request for the mycology patient testing from an authorized person. Refer to D5301. 3. The laboratory failed to use the potassium hydroxide (KOH) reagent before the manufacturer's expiration date. Refer to D5417. 4. The laboratory failed to perform and document the microscope maintenance for the mycology and parasitology testing. Refer to D5429. 5. The laboratory failed to perform and document media checks for the ACU-DTM (Dermatophyte Test Medium). Refer to D5477. 6. The laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor the laboratory systems. Refer to D5791. 7. The laboratory failed to establish a system to ensure the manually entered patient final test results were entered into the patient's electronic medical record chart. Refer to D5801.

**D5209**

**PERSONNEL COMPETENCY ASSESSMENT POLICIES**

CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

. Based on record review and interview, the laboratory failed to ensure written competency policies contained the six requirements from subpart M and was implemented for three (#1 - #3) of three testing personnel performing the mycology potassium hydroxide (KOH) and parasitology testing for two (May 2016 to May 2018) of two years. Findings include: 1. On May 14, 2018 at 9:50 AM, record review revealed the laboratory established a written competency policy. The policy did not include the six requirements from subpart M as follows for the mycology and parasitology testing: a. Direct observations of routine patient test performance, patient preparation, specimen handling, processing, and testing. b. Monitoring the recording and reporting of patient test results. c. Review of test results, worksheets, quality control records, proficiency testing results, and preventive maintenance. d. Direct observation of performance of instrument maintenance and function checks. e. Assessment of test performance through testing previously analyzed samples. f. Assessment of problem solving skills. 2. On May 14, 2018 at 9:50 AM, record review revealed the laboratory did not have any documentation to show the annual competency assessments were performed and documented for three (#1, #2, and #3) of three testing personnel performing the mycology and parasitology testing in 2016, 2017, and 2018. 3. During the interview on May 14, 2018 at 9:50 AM, an office staff member confirmed the laboratory did not establish a competency policy that contained the six requirements from Subpart M and did not implement the policy in 2016, 2017, and 2018. \*\*\*Repeat Deficiency from April 8, 2016 survey\*\*\*

**D5301**

**TEST REQUEST**

CFR(s): 493.1241(a)

The laboratory must have a written or electronic request for patient testing from an authorized person.

This STANDARD is not met as evidenced by:

. Based on document review and interview, the laboratory failed to have an electronic request for the mycology patient testing from an authorized person for one (#9) of nine patient charts audited. Findings include: 1. On May 14, 2018 at 11:25 AM, document review for one (#9) of nine patient charts audited revealed the laboratory did not have an electronic request for the mycology potassium hydroxide testing by an authorized person in the patient's electronic medical record (EMR) chart. 2. During the interview on May 14, 2018 at 11:25 AM, an office staff member confirmed an electronic request for the mycology KOH testing was not present in the patients EMR chart.

**D5417**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(d)

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.

This STANDARD is not met as evidenced by:

. Based on observation, record review, and interview, the laboratory failed to use the mycology potassium hydroxide (KOH) reagent before the manufacturer's expiration date for five (#5-#9) of nine patient charts audited. Findings include: 1. During a tour of the laboratory on May 14, 2018 at approximately 9:07 AM, the surveyor observed potassium hydroxide in use with an expiration date of December 3, 2014 recorded on the manufacturer's label. 2. On May 14, 2018 at approximately 11:25 AM, record review revealed for five (#5-#9) of nine patient charts audited the KOH reagent in use on the day of the testing was expired. 3. During the interview on May 14, 2018 at approximately 9:07 AM, an office staff member confirmed the KOH reagent was used past the manufacturer's stated expiration date.

**D5429**

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

. Based on record review and interview, the laboratory failed to perform and document the microscope maintenance for the mycology and parasitology testing for 1) each day of use for three (#5, #6, and #8) of nine patient charts audited and 2) the annual grounding and ocular calibration for two (2016 and 2017) of two years reviewed. Findings include: 1. On May 14, 2018 at 10:21 AM, record review of the microscope maintenance log revealed the laboratory did not perform and document the maintenance as follows: a. no documentation of the microscope daily maintenance

for three (#5, #6, and #8) of nine patient charts audited b. no annual documentation of the microscope grounding and ocular calibration for two (2016 and 2017) of two years reviewed. 2. During the interview on May 14, 2018 at 10:21 AM, an office staff member confirmed the microscope maintenance was not performed and documented as required.

**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, the laboratory failed to perform and document media checks for the ACU-DTM (dermatophyte test medium) with each new batch, lot, or shipment including: the sterility, the ability to support growth, inhibition of growth, and the physical characteristics for 24 (May 2016 to May 2018) of 24 months reviewed. Findings include: 1. On May 14, 2018 at 10:10 am, record review of the "DTM Test Specimens" log revealed for 24 (May 2016 to May 2018) of 24 months the laboratory failed to perform and document for each new batch, lot, or shipment of DTM media: the sterility, the ability to support growth, inhibition of growth, and the physical characteristics as follows: a. May to December 2016 - no documentation of sterility, the ability to support growth, inhibition of growth, and the physical characteristics. b. February 8, 2018 - no documentation of sterility, inhibition of growth, and the physical characteristics c. January to May 2018 - no documentation of sterility, ability to support growth, inhibition of growth, and the physical characteristics for the current lot (D-1227-0517) in use. 2. During the interview on May 14, 2018 at 10:10 AM, an office staff member confirmed the media checks were not performed and documented as required.

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:  
. Based on review of the quality assurance policy and interview, the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor the laboratory systems for two (May 2016 to May 2018) of two years. Findings include: 1. On May 14, 2018 at 9:20 AM, the surveyor reviewed the following quality assurance policies: a. "Quality Assurance Laboratory Policy" b. "Ferrera Dermatology Quality Assurance Audit - Patient Chart Review" 2. On May 14, 2018 at 9:20 AM when queried, there was no documentation to show the laboratory had performed the

quality assurance checks and the patient chart reviews for 24 (May 2016 to May 2018) of 24 months of operation. 3. During the interview on May 14, 2018 at 9:20 AM, an office staff member confirmed the quality assurance checks were not performed and documented. \*\*\*Repeat Deficiency from February 7, 2012 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:

. Based on record review and interview, the laboratory failed to establish a system to ensure the manually entered patient final test results were entered into the patient's electronic medical record (EMR) for one (#9) of nine patient charts audited. Findings include: 1. On May 14, 2018 at 11:25 AM, record review for one (#9) of nine patient charts audited revealed the final patient test result for the mycology potassium hydroxide (KOH) testing was not included in the patient's EMR chart. 2. On May 14, 2018 at 11:25 AM when queried, an office staff member was unable to provide the surveyor the final patient test result in the patient's EMR chart. 3. During the interview on May 14, 2018 at 11:25 AM, an office staff member confirmed the final KOH testing results were not included in the patient's EMR chart.