

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D0719175	<b>(X3) Date Survey Completed</b>  07/17/2024
<b>Name of Provider or Supplier</b>  Farmington Dermatologists	<b>Street Address, City, State</b>  23133 Orchard Lake Road Suite 201, Farmington, 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>D3043</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(7)</p> <p>The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen.</p> <p>This STANDARD is not met as evidenced by:                      . Based on record review and interview with the Office Manager, the laboratory failed to retain histopathology slides for at least 10 years for 17 of 27 cases performed from July 17, 2014 to August 28, 2014. Findings include: 1. A review of patient histopathology slides and the laboratory's testing logs revealed the following cases missing slides: a. COS14-127 performed on 7/17/14. b. COS14-128 performed on 7/17/14. c. COS14-129 performed on 7/17/14. d. COS14-130 performed on 7/22/14. e. COS14-131 performed on 7/22/14. f. COS14-132 performed on 7/22/14. g. COS14-133 performed on 7/22/14. h. COS14-134 performed on 7/23/14. i. COS14-135 performed on 7/23/14. j. COS14-136 performed on 7/28/14. k. COS14-137 performed on 7/28/14. l. COS14-138 performed on 7/28/14. m. COS14-139 performed on 7/29/14. n. COS14-140 performed on 8/4/14. o. COS14-141 performed on 8/4/14. p. COS14-142 performed on 8/5/14. q. COS14-143 performed on 8/5/14. 2. An interview on 7/17/24 at 12:06 pm with the Office Manager confirmed the cases listed above did not have histopathology slides available.</p>
<b>D5006</b>	<p><b>MYCOLOGY</b> CFR(s): 493.1203</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.

This CONDITION is not met as evidenced by:

. Based on observations, record review, and interviews, the laboratory failed to establish a competency assessment policy to assess testing personnel competency (refer to D5209), failed to verify the accuracy of its testing at least twice annually (refer to D5217), failed to ensure media supporting the growth of its control organisms had not deteriorated (refer to D5417 A), the laboratory failed to perform controls to ensure media sterility, inhibition of growth of organisms, and produce a color change for two lots of Dermatophyte Test Medium (DTM) used in fungal culture testing (refer to D5477), and failed to ensure fungal culture test results were accurately recorded on the test report (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 with the Office Manager, the laboratory failed to establish a competency assessment policy to assess testing personnel competency for one of one testing personnel listed on Form CMS-209. Findings include: 1. A review of the laboratory's "Personnel Assessment" policy revealed a section stating, "At least annually, the laboratory director and/or technical consultant will review the performance of each staff member working in the lab to assure employee competency." No process was present to assess the competency of the testing personnel also serving as the laboratory director and technical consultant. 2. A review of Testing Personnel #1's competency assessment records revealed a lack of competency assessments performed in 2023 for fungal cultures, dermatopathology, Potassium Hydroxide (KOH) preparations, and Scabies preparations. 3. An interview on 7/17/24 at 12:13 pm with the Office Manager confirmed a lack of policy to assess the competency of Testing Personnel #1 serving the roles of laboratory director and technical consultant.

**D5217**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**  
CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Office Manager, the laboratory failed to verify the accuracy of its testing at least twice annually for two (July 2022 to July 2024) of 2 years reviewed. Findings include: 1. A review of the laboratory's "Comparison of Test Results/Split Testing" policy revealed a section stating, "The laboratory will verify the accuracy of any instruments that are not enrolled in a

proficiency testing program. It will do so by running at least 2-5 specimens (a specimen that is divided into two parts after collection- the laboratory analyzes one portion and the other is sent to a reference lab." The policy did not address how it would verify the accuracy of testing where splitting a specimen would not be possible for Potassium Hydroxide (KOH) and scabies preparations. 2. A review of the laboratory's records revealed a lack of twice annual verification of accuracy testing for its fungal cultures, KOH preparations, scabies preparations, and dermatopathology testing. 3. An interview on 7/17/24 at 12:13 pm with the Office Manager confirmed the laboratory had not performed verification of accuracy testing for two years.

**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:  
. A. Based on observation and interview with the Office Manager, the laboratory failed to ensure media supporting the growth of its control organisms had not deteriorated for all control organism cultures observed. Findings include: 1. The surveyor observed three ACU-DTM culture bottles with "T. MENTAG", "A. NIGER", and "C. ALBICANS" written on the labels. The media had dried completely. 2. A review of the laboratory's "Test Methods, Equipment, Reagents, Materials, and Supplies" policy revealed a section stating, "Reagents, solutions, culture media, control materials, calibration materials and other supplies are not used when they have exceeded their expiration dates, have deteriorated or are of substandard quality." 3. An interview on 7/17/24 at 9:21 am with the Office Manager confirmed the organisms on the media observed were to be used as control organisms for the next new lot of media and the media it was on had dried out completely. B. Based on observation and interview with the Office Manager, the laboratory failed to ensure specimen collection tubes had not exceeded expiration dates for two of two collection tubes available for use. Findings include: 1. The surveyor observed two red top vacutainer tubes with the expiration date of 6/30/23 on 7/17/24 at 9:26 am. 2. A review of the laboratory's "Test Methods, Equipment, Reagents, Materials, and Supplies" policy revealed a section stating, "Reagents, solutions, culture media, control materials, calibration materials and other supplies are not used when they have exceeded their expiration dates, have deteriorated or are of substandard quality." 3. An interview on 7/17/24 at 9:26 am with the Office Manager revealed the tubes were used to collect differential biopsies and confirmed the tubes had expired.

**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, the laboratory failed to perform controls to ensure media sterility, inhibition of growth of organisms, and produce a color change for two lots of Dermatophyte Test Medium (DTM) used in fungal culture testing from July 2022 to July 2024. Findings include: 1. A review of the laboratory's quality control testing documentation revealed a lack of sterility control, inhibition of growth control, and results of organisms that would cause the DTM to change color to read for the following lots in use between July 2022 and July 2024: a. Lot D-1403-0121 expiration date 1/25/23. b. Lot D-1474-0822 expiration date 8/30/24. 2. A review of the patient testing log revealed a total of 11 patients had fungal culture testing reported using the two lots of DTM listed above between July 2022 and July 2024. 3. A review of the laboratory's "Instructions for DTM Q.C. Kit" stating, "Inoculate one test vial with the dermatophyte, T. mentagrophyte. This will serve as the Positive Control. The remaining vials are to be inoculated with the following saprophyte and competing organisms: a. Vial #2- Aspergillus niger (Saprophyte). b. Vial #3- Candida albicans (Yeast). c. Vial #4 Escherichia coli (Negative Control)." The instructions did not include a process for assessing the sterility for each batch of media. 4. An interview on 7/17/24 at 10:05 am with the Office Manager confirmed the laboratory had not been performing sterility and inhibition controls and had not recorded the results of biochemical color change responses for organisms with growth but no color change.

**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 with the Office Manager, the laboratory failed to ensure fungal culture test results were accurately recorded on the test report for three (Patients 3-5) of five fungal culture patient test records reviewed. Findings include: 1. A review of the laboratory's patient testing log revealed the following patients with fungal cultures performed with the results: a. Patient 3 had their specimen collected on 3/7/23 and the result of no growth. b. Patient 4 had their specimen collected on 5/12/23 and the result of no growth. c. Patient 5 had their specimen collected on 8/1/23 and the result of no growth. 2. A review of the laboratory's patient test reports revealed the following results for the same patients listed above: a. Patient 3 had a result of "Growth" issued on 3/21/23. b. Patient 4 had no culture results and the test report date of 5/26/23. c. Patient 5 had no culture results and the test report date of 8/15/23. 3. An interview on 7/17/24 at 12:13 pm with the Office Manager confirmed the patients listed above had inaccurate test reporting.

**D6076**

**LABORATORY DIRECTOR**  
 CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

. Based on observations, record review, and interviews, the Laboratory Director failed to verify the accuracy of its testing at least twice annually (Refer to D6086), failed to ensure media supporting the growth of its control organisms had not deteriorated (refer to D6093 A), failed to ensure control performance of media sterility, inhibition of growth of organisms, and produce a color change for two lots of Dermatophyte Test Medium (DTM) used in fungal culture testing (refer to D6093 B), failed to ensure fungal culture test results were accurately recorded on the test report (refer to D6098), and failed to ensure a competency assessment policy to assess testing personnel competency was established (refer to D6101).

**D6086**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

This STANDARD is not met as evidenced by:

. Based on record review and interview, the Laboratory Director failed to verify the accuracy of its testing at least twice annually. Refer to D5217.

**D6093**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

. A. Based on observation, record review, and interview, the Laboratory Director failed to ensure media supporting the growth of its control organisms had not deteriorated. Refer to D5417 A. B. Based on record review and interview, the Laboratory Director failed to ensure control performance of media sterility, inhibition of growth of organisms, and produce a color change for two lots of Dermatophyte Test Medium (DTM) used in fungal culture testing. Refer to D5477.

**D6098**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(8)

The laboratory director must ensure that reports of test results include pertinent information required for interpretation.

This STANDARD is not met as evidenced by:

. Based on record review and interview, the Laboratory Director failed to ensure fungal culture test results were accurately recorded on the test report. Refer to D5801.

**D6101**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(11)

The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart.

This STANDARD is not met as evidenced by:

. Based on record review and interview, the Laboratory Director failed to ensure a competency assessment policy to assess testing personnel competency was established. Refer to D5209.