

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0956762	(X3) Date Survey Completed 12/18/2024
Name of Provider or Supplier Dermatology & Skin Surgery Center	Street Address, City, State 300 E Maiden Ln, St Joseph, 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 observation, record review and interviews, the laboratory failed to establish competency assessment policies to assess testing personnel (refer to D5209), failed to have a request for testing (refer to D5301), failed to have the laboratory director approve, sign, and date its Potassium Hydroxide (KOH) testing procedure prior to use (refer to D5407), failed to ensure its Potassium Hydroxide (KOH) solution had not exceeded expiration dates (refer to D5417), and failed to have a test reports (refer to D5801).</p>
D5008	<p>PARASITOLOGY CFR(s): 493.1204</p> <p>If the laboratory provides services in the subspecialty of Parasitology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1264, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: . Based on observation, record review and interviews, the laboratory failed to establish competency assessment policies to assess testing personnel (refer to D5209), failed to have a request for testing (refer to D5301), failed to have the laboratory director</p>

approve, sign, and date its Scabies preparation testing procedure prior to use (refer to D5407), failed to ensure its Potassium Hydroxide (KOH) solution had not exceeded expiration dates (refer to D5417), and failed to have test reports (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 competency assessment policies to assess testing personnel for one (2024) of two years reviewed. Findings include: 1. A review of the testing personnel competency assessments revealed blank forms with the names of testing personnel #1 and #2 on them and the dates of 12/12/24 and 12/5/24, respectively. Both personnel perform Potassium Hydroxide (KOH) and Scabies preparations. No competency assessments were performed for testing personnel #1 and #2 since 1/14/23. 2. A review of the laboratory's policies and procedures revealed a lack of competency assessment policy established. 3. An interview on 12/18/24 at 2:50 pm with the office manager confirmed a competency assessment policy had not been established.

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 record review and interview with office personnel #1, the laboratory failed to have a request for testing for two (patients #2 and #5) of six patient test records reviewed. Findings include: 1. A review of the laboratory's testing logs revealed patient #2 received Potassium Hydroxide (KOH) testing on 8/1/23 and patient #5 received Scabies testing on 6/5/23. 2. A review of patient test requests revealed a lack of documentation for patients #2 and #5. 3. An interview on 12/18/24 at 1:50 pm with office personnel #1 confirmed the lack of test requests for patients #2 and #5. ***This is a repeated deficiency from the 7/24/19 recertification survey.***

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the office manager, the laboratory failed to have the laboratory director approve, sign, and date its Potassium Hydroxide (KOH) and Scabies preparation testing procedures prior to use for two (December 2022 to December 2024) of two years reviewed. Findings include: 1. A review of the

	<p>laboratory's procedure manuals revealed a lack of policies and procedures for KOH and Scabies preparation testing. 2. The surveyor requested the policies and procedures on 12/18/24 at 2:44 pm and was provided with a blue folder containing unapproved copies of KOH, Scabies, Tzank, and histopathology procedures. 3. An interview on 12/18/24 at 2:44 pm with the office manager confirmed the procedures provided were not approved, signed, or dated by the laboratory director and the laboratory had not performed Tzanck smears or histopathology testing. ***This is a repeated deficiency from the 3/15/23 recertification survey.***</p>
<p>D5417</p>	<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 observation and interview with the office manager, the laboratory failed to ensure its Potassium Hydroxide (KOH) solution had not exceeded expiration dates for 14 patients tested since the bottle had expired. Findings include: 1. The surveyor observed a bottle of Potassium Hydroxide (KOH) near the microscope with the expiration date of 9/21/23 and an open date of 11/1/21 written on the bottle on 12/18/24 at 2:38 pm. 2. An interview on 12/18/24 at 2:44 pm with the office manager confirmed the KOH bottle had exceeded its expiration date. 3. A review of the laboratory's patient testing logs revealed 14 patients received testing since the KOH bottle expired.</p>
<p>D5801</p>	<p>TEST REPORT CFR(s): 493.1291(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with office personnel #1, the laboratory failed to have a test report for two (patients #2 and #5) of six patient test records reviewed. Findings include: 1. A review of the laboratory's testing logs revealed patient #2 received Potassium Hydroxide (KOH) testing on 8/1/23 and patient #5 received Scabies testing on 6/5/23. 2. A review of patient test reports revealed a lack of documentation for patients #2 and #5. 3. An interview on 12/18/24 at 1:50 pm with office personnel #1 confirmed the lack of test reports for patients #2 and #5. ***This is a repeated deficiency from the 7/24/19 recertification survey.***</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p>

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

. Based on observation, record review, and interviews, the laboratory director failed to ensure its Potassium Hydroxide (KOH) solution had not exceeded expiration dates (refer to D6004), failed to establish competency assessment policies to assess testing personnel competency (refer to D6014), failed to ensure quality assessment programs were maintained to monitor its Potassium Hydroxide (KOH) and Scabies preparation testing (refer to D6021), and failed to approve, sign, and date its Potassium Hydroxide (KOH) and Scabies preparation testing procedures prior to use (refer to D6031).

D6004

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

. Based on observation and interview with the office manager, the laboratory director failed to ensure its Potassium Hydroxide (KOH) solution had not exceeded expiration dates. Refer to D5417.

D6014

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(3)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the office manager, the laboratory director failed to establish competency assessment policies to assess testing personnel competency. Refer to D5209.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the office manager, the laboratory director failed to ensure quality assessment programs were maintained to monitor its Potassium Hydroxide (KOH) and Scabies preparation testing for two (December 2022 to December 2024) of two years reviewed. Findings include: 1. A review of the laboratory's "Quality Assurance" policy revealed a section stating, "Every six months log books are to be checked for accuracy. Ten or so charts will be chosen at random from the KOH, DTM, Tzank, scabies, and Mohs carts. These charts are to be checked by making sure all information in the log is in the chart. All results are to be logged on Quality Assessment chart review sheets located in the QA binder located in the lab. Every year manuals for equipment and procedure protocols will be reviewed. All manuals, logs, and tests will be reviewed, signed, and dated by (laboratory director) as designated in every protocol." 2. A review of the laboratory's quality assessment documentation revealed the most recent completed form was for the review period of July 2022 to December 2022. 3. An interview on 12/18/24 at 2:44 pm with the office manager confirmed quality assessment documentation was not present.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(13)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

. Based on record review and interview with the office manager, the laboratory director failed to approve, sign, and date its Potassium Hydroxide (KOH) and Scabies preparation testing procedures prior to use. Refer to D5407.