

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2101783	(X3) Date Survey Completed 08/05/2025
Name of Provider or Supplier Ganger Dermatology	Street Address, City, State 1979 Huron Parkway, Ann Arbor, 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
D5423	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)</p> <p>Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.</p> <p>This STANDARD is not met as evidenced by: . Based on a lack of documentation and interview with testing personnel #3, the laboratory failed to establish performance specifications for its Potassium Hydroxide (KOH) mycology testing prior to reporting patient test results for four (April 2025 to August 2025) of four months since the laboratory started patient testing. Findings include: 1. A review of the laboratory's patient test records revealed patient KOH testing started 4/30/25. 2. The surveyor requested the laboratory's performance specifications for its KOH testing on 8/5/25 at 9:37 am and they were not made available. 3. An interview on 8/5/25 at 9:37 am with testing personnel #3 confirmed the laboratory had not established performance specifications for its KOH testing prior to testing patients.</p>
D6000	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.</p>

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 record review, lack of documentation and interviews, the laboratory director failed to ensure performance specifications were established for its Potassium Hydroxide (KOH) mycology testing prior to reporting patient test results (refer to D6012), failed to have a qualified technical consultant for its moderate complexity mycology testing (refer to D6028), and failed to ensure that prior to testing patient specimens, testing personnel #1 received training to perform the laboratory's service of Potassium Hydroxide (KOH) testing and demonstrated accurate and reliable test performance (refer to D6029).

D6012

LABORATORY DIRECTOR RESPONSIBILITIES

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

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)(ii) The test methodologies selected have the capability of providing the quality of results required for patient care;

This STANDARD is not met as evidenced by:

. Based on a lack of documentation and interview with testing personnel #3, the laboratory director failed to ensure performance specifications were established for its Potassium Hydroxide (KOH) mycology testing prior to reporting patient test results. Refer to D5423.

D6028

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(10)

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)(10) 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 a lack of documentation, the laboratory director failed to have a qualified technical consultant for its moderate complexity mycology testing. Refer to D6035.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

. Based on record review, a lack of documentation, and interview with testing personnel #3, the laboratory director failed to ensure that prior to testing patient specimens, testing personnel #1 received training to perform the laboratory's service of Potassium Hydroxide (KOH) testing and demonstrated accurate and reliable test performance for four (April 2025 to August 2025) of four months since testing personnel #1 started performing patient testing. Findings include: 1. A review of the laboratory's patient test records revealed testing personnel #1 started patient KOH testing started 4/30/25. 2. A review of the testing personnel #1's records revealed a lack of training documentation. 3. An interview on 8/5/25 at 9:12 am with testing personnel #3 confirmed testing personnel #1 did not have documentation of laboratory training performed prior to performing patient testing.

D6033

TECHNICAL CONSULTANT-MODERATE COMPEXITY
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

. Based on record review and a lack of documentation, the laboratory failed to have a qualified technical consultant for its moderate complexity mycology testing. Refer to D6035.

D6035

TECHNICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's

degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:

. Based on record review and a lack of documentation, the laboratory failed to have a qualified technical consultant for its moderate complexity mycology testing for four (April 2025 to August 2025) of four months since the laboratory started performing mycology patient testing. Findings include: 1. A review of the laboratory's Form CMS-209 revealed the laboratory director was listed as serving as the technical consultant over its Potassium Hydroxide (KOH) mycology testing. 2. A review of the laboratory director's qualifications revealed a State of Michigan Medical Doctor's license and a lack of at least one year of laboratory training or experience, or both in non-waived mycology testing. 3. The surveyor requested documentation of at least one year of laboratory training or experience, or both in non-waived mycology testing on 8/5/25 at 9:10 am and it was not made available. 4. The laboratory was given an additional seven days to provide the missing documentation, and it was not received.