

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D1104243	(X3) Date Survey Completed 08/07/2025
Name of Provider or Supplier Pinnacle Dermatology	Street Address, City, State 37605 Pembroke Avenue, Livonia, 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
D0000	A recertification survey was performed on August 7, 2025 by the State of Michigan Licensing and Regulatory Affairs Department. The laboratory was found to be out of compliance with CLIA regulations (42 CFR Part 493, Laboratory Requirements) for the following Condition-level deficiency: 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with laboratory manager, the laboratory failed to verify its ectoparasite testing at least twice annually for two (August 2023 to August 2025) of two years reviewed. Findings include: 1. A review of the laboratory's Form CMS-116 revealed the laboratory listed "Mohs Dermatopathology" and "KOH prep" as testing performed at the laboratory under the specialties of histopathology and mycology respectively. 2. During the survey entrance conference, the surveyor asked if the laboratory was performing parasitology testing in addition to the Potassium Hydroxide (KOH) testing listed on Form CMS-116 on 8/7/25 at 8:59 am with the laboratory manager and they confirmed the laboratory had not been performing ectoparasite testing. 3. A review of patient test reports revealed patient #5 had KOH testing ordered and performed on 4/18/25 with the result of "demodex", an ectoparasite. 4. A review of the laboratory's "Ectoparasites" test procedure revealed a section titled "Quality Control Procedures" stating, "Since there do not seem to be any suitable, commercially available control materials for this procedure or routine methods for culture of ectoparasites, one or more of the following options may be used to perform the required analysis of the quality of the results obtained. Test each patient specimen in duplicate as well as having second provider (MD, RN, PA) review</p>

specimen. Bi-annual minimum secondary evaluation mandatory per CLIA standard." 5. A review of the laboratory's procedure manual revealed a test procedure titled "Ectoparasites" with the following laboratory director approval dates: a. 5/22/22 b. 5/30/23 c. 5/25/24 d. 5/26/25 6. A review of the laboratory's twice annual verification of accuracy documentation revealed a lack of twice annual verification of accuracy testing performed in 2023, 2024, and 2025.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the laboratory manager, the laboratory failed to include the reportable range for its Potassium Hydroxide (KOH) mycology testing for two (August 2023 to August 2025) of two years reviewed. Findings include: 1. A review of the laboratory's Form CMS-116 revealed the laboratory listed "Mohs Dermatopathology" and "KOH prep" as testing performed at the laboratory under the specialties of histopathology and mycology respectively. 2. A review of patient test reports revealed patient #5 had KOH testing ordered and performed on 4/18/25 with the result of "demodex", an ectoparasite. 3. A review of the laboratory's "Potassium Hydroxide (KOH)" test procedure revealed a lack of reportable range. 4. An interview on 8/7/25 at 10:41 am with the laboratory manager confirmed the result of demodex was not an appropriate result for a KOH test looking for fungal elements. ***This is a repeated deficiency from the July 25, 2023 recertification survey.***

D5801

TEST REPORT
CFR(s): 493.1291(a)

(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 laboratory manager, the laboratory failed to ensure patient test reports included accurate patient specimen case identification for one (patient #9) of nine patients receiving dermatopathology testing reviewed. Findings include: 1. A review of patient #9's mohs surgery case from 6/26 /25 revealed the mohs map included the case number "LMS25-109" and the patient chart included the case number of "LMS25-110". 2. A review of the laboratory's patient testing logs revealed "LMS25-110" was assigned to a different patient. 3. An interview on 8/7/25 at 10:55 am with the laboratory manager confirmed the discrepancy listed above.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

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 record review and interviews, the laboratory director failed to notify the State Agency when adding a new testing specialty in accordance with 493.51 (refer to D6004), failed to ensure its ectoparasite testing was verified at least twice annually (refer to D6013), and failed ensure to the reportable range for its Potassium Hydroxide (KOH) mycology testing was included in the laboratory's test procedure (refer to D6014).

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 record review and interview with the laboratory manager, the laboratory director failed to notify the State Agency when adding a new testing specialty in accordance with 493.51 for three (2022 to 2025) of three years since the test procedure was approved. Findings include: 1. A review of the laboratory's Form CMS-116 revealed the laboratory listed "Mohs Dermatopathology" and "KOH prep" as testing performed at the laboratory under the specialties of histopathology and mycology respectively. 2. During the survey entrance conference, the surveyor asked

if the laboratory was performing parasitology testing in addition to the Potassium Hydroxide (KOH) testing listed on Form CMS-116 on 8/7/25 at 8:59 am with the laboratory manager and they confirmed the laboratory had not been performing ectoparasite testing. 3. A review of the laboratory's procedure manual revealed a test procedure titled "Ectoparasites" with the following laboratory director approval dates: a. 5/22/22 b. 5/30/23 c. 5/25/24 d. 5/26/25 4. A review of patient test reports revealed patient #5 had KOH testing ordered and performed on 4/18/25 with the result of "demodex", an ectoparasite. 5. The surveyor reviewed the CMS database for the laboratory revealed a lack of documentation of adding parasitology testing in accordance with 493.51 Notification requirements for laboratories issued a certificate of compliance, which states, "Laboratories issued a certificate of compliance must meet the following conditions: Notify HHS no later than 6 months after any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate of compliance."

D6013

LABORATORY DIRECTOR RESPONSIBILITIES

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

(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

This STANDARD is not met as evidenced by:

. Based on record review and interview with laboratory manager, the laboratory director failed to ensure its ectoparasite testing was verified at least twice annually. Refer to D5217.

D6014

LABORATORY DIRECTOR RESPONSIBILITIES

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

(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 laboratory manager, the laboratory director failed ensure to the reportable range for its Potassium Hydroxide (KOH) mycology testing was included in the laboratory's test procedure. Refer to D5403.