

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D1096986	<b>(X3) Date Survey Completed</b>  09/25/2025
<b>Name of Provider or Supplier</b>  Wayne Health	<b>Street Address, City, State</b>  1310 N Macomb Street, Monroe, 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>D0000</b>	<p>. Based on record review and interview with the laboratory director, the laboratory failed to notify the state agency prior to performing and reporting results for its high complexity dermatopathology microscopic tissue examinations, in accordance with 493.53 Notification requirements for laboratories issued a certificate for provider-performed microscopy (PPM) procedures, for 10 (January 2024 to October 2024) of 10 months the laboratory was performing microscopic tissue examinations prior to notifying the state agency. Findings include: 1. A review of the CMS database showed the laboratory had applied for a certificate of compliance and had a certificate of registration, which was effective 10/1/24. 2. A review of the laboratory's patient biopsy logs revealed documentation starting 1/4/24. A total of 199 patients had biopsies collected between 1/4/24 and 10/1/24. 3. A review of five test reports for patients listed on the patient biopsy logs between January 2024 and October 2024 confirmed patients listed on the biopsy logs had received dermatopathology microscopic tissue examinations at the laboratory. a. Patient #3 received testing on 01/25/2024. b. Patient #4 received testing on 03/14/2024. c. Patient #5 received testing on 05/30/2024. d. Patient #6 received testing on 07/25/2024. e. Patient #7 received testing on 09/04/2024. 4. A review of the laboratory's certification history showed the laboratory had an active certificate for provider-performed microscopy (PPM) procedures from 7/24/23 to 9/30/24. A CMS-116 form was received to perform the change in certificate type indicated to be effective on 10/1/24. The laboratory failed to notify the state agency in accordance with 493.53 Notification requirements for laboratories issued a certificate for provider-performed microscopy (PPM) procedures, which states, "Laboratories issued a certificate for PPM procedures must notify HHS or its designee-- (a) Before performing and reporting results for any test of moderate or high complexity, or both, in addition to tests specified as PPM procedures or any test or examination that is not specified under 493.15(c), for which it does not have a registration certificate as required in subpart C or subpart D, as applicable, of this part." 5. An interview on 9/25/25 at 11:16 am with the laboratory director acknowledged the above findings.</p>
<b>D5209</b>	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 laboratory director, the laboratory failed to follow its competency assessment policies for one (2024) of two years reviewed. Findings include: 1. A review of the laboratory's "CLIA Certification Exam" policy revealed a section stating, "To ensure twice annually the laboratory must verify the accuracy of testing for each provider using the Michigan Dermatological Society [sic]. Physicians performed microscopy/DTM interpretation and/or dermatopathology examination." 2. A review of the laboratory's Michigan Dermatological Society exam records for testing personnel #1 revealed a lack of documentation for any performed in 2024. 3. An interview on 9/25/25 at 11:16 am with the laboratory director acknowledged the above findings.

**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:

. A. Based on record review and interview with the laboratory director, the laboratory failed to verify the accuracy of its Potassium Hydroxide (KOH) and Scabies preparations at least twice annually for two (September 2023 to September 2025) of two years reviewed. Findings include: 1. A review of the laboratory's verification of accuracy data revealed a lack of verification of accuracy data for its KOH and Scabies preparations between September 2023 to September 2025. 2. An interview on 9/25/25 at 11:16 am with the laboratory director acknowledged the above findings. B. Based on record review and interview with the laboratory director, the laboratory failed to verify the accuracy of its dermatopathology testing at least twice annually for one (2024) of two years reviewed. Findings include: 1. A review of the laboratory's verification of accuracy data revealed a lack of verification of accuracy data for its dermatopathology testing prior to 3/15/25. 2. An interview on 9/25/25 at 11:16 am with the laboratory director acknowledged the above findings.

**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 director, the laboratory failed to include the detection of inadequately prepared slides in its test procedures for dermatopathology testing for 20 (January 2024 to September 2025) of 20 months since the laboratory started dermatopathology testing. Findings include: 1. A review of the laboratory's "Quality Control Assessment", "Collection and Interpretation of Pathology Specimens", and "Histopathology" procedures revealed a lack of detection of inadequately prepared slides. 2. An interview on 9/25/25 at 11:16 am with the laboratory director acknowledged the above findings.

**D5407**

PROCEDURE MANUAL  
CFR(s): 493.1251(d)

(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 laboratory director, the laboratory failed to use test procedures approved, signed, and dated by the laboratory director for two (September 2023 to September 2025) of two years reviewed. Findings include: 1. A review of the laboratory's procedure revealed a lack of laboratory director's signature and date showing the procedures were approved. 2. An interview on 9/25/25 at 11:16 am with the laboratory director acknowledged the above findings.

**D5473**

CONTROL PROCEDURES  
CFR(s): 493.1256(e)(2)(g)

(e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate.

This STANDARD is not met as evidenced by:  
. Based on record review and interview with the laboratory director, the laboratory failed to assess stained tissue for intended reactivity for 20 (January 2024 to September 2025) of 20 months since the laboratory started dermatopathology testing. Findings include: 1. A review of the laboratory's testing logs revealed the laboratory started performing dermatopathology testing on 1/4/24. 2. The surveyor requested documentation of the laboratory's stain quality records and positive and negative

reactivity of stains used in dermatopathology testing from January 2024 to September 2025 on 9/25/25 at 10:36 am and it was not made available. 3. An interview on 9/25/25 at 11:16 am with the laboratory director acknowledged the above findings.

**D5805**

**TEST REPORT**  
CFR(s): 493.1291(c)

(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:  
. Based on record review and interviews, the laboratory failed to include the name and address of the laboratory performing gross specimen examinations for 10 (Patients 3-12) of 10 patient test reports for dermatopathology testing reviewed. Findings include:  
1. An interview with testing personnel #2 at 10:36 am revealed the laboratory sends its tissue specimens to a reference laboratory for grossing and processing. Once processed, the reference laboratory sends the slides to the laboratory for interpretation.  
2. A review of 10 patient test reports revealed tissue grossing information but lacked the name and address of the laboratory that had performed the tissue grossing for the following: a. Patient #3 receiving testing on 01/25/2024. b. Patient #4 receiving testing on 03/14/2024. c. Patient #5 receiving testing on 05/30/2024. d. Patient #6 receiving testing on 07/25/2024. e. Patient #7 receiving testing on 09/04/2024. f. Patient #8 receiving testing on 12/13/2024. g. Patient #9 receiving testing on 02/27/2025. h. Patient #10 receiving testing on 04/25/2025. i. Patient #11 receiving testing on 06/20/2025. j. Patient #12 receiving testing on 08/08/2025. 3. An interview on 9/25/25 at 11:16 am with the laboratory director acknowledged the above findings.