

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 23D2054540	<b>(X3) Date Survey Completed</b> 05/12/2025
<b>Name of Provider or Supplier</b> Wayne Health - Canfield And Tolan Park	<b>Street Address, City, State</b> 50 E Canfield Ste 101-S, Detroit, 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>	A recertification survey was performed on May 12, 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, effective April 24, 2003) for the following condition-level deficiency: 493.801 Condition: Enrollment and testing of samples.
<b>D2000</b>	<p><b>ENROLLMENT AND TESTING OF SAMPLES</b> CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: . Based on record review and interview with the technical consultant, the laboratory failed to enroll in proficiency testing for its Human Immunodeficiency Virus (HIV) testing and missed two (2024 event one and 2025 event one) of six proficiency testing events reviewed. Findings include: 1. A review of the laboratory's HIV proficiency testing records revealed a lack of participation in 2024 event one and 2025 event one. 2. An interview on 5/12/25 at 10:05 am with the technical consultant confirmed the laboratory had not enrolled in 2024 and 2025 in time to receive the first events of each year.</p>
<b>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p>

(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the technical consultant, the laboratory director and testing personnel failed to attest to the routine integration of the samples into the patient workload for one (2024 VM-C) of four proficiency testing events reviewed. Findings include: 1. A review of the laboratory's College of American Pathologists' proficiency testing records revealed a lack of signed attestations attest to the routine integration of the Human Immunodeficiency Virus (HIV) proficiency testing samples into the patient workload during event 2024 VM-C. 2. The surveyor requested the missing attestation forms on 5/12/25 at 10:08 am and 10:17 am and they were not made available. 3. An interview on 5/12/25 at 11:50 am with the technical consultant confirmed the signed attestation statements for the event 2024 VM-C were not present.

**D3037**

**RETENTION REQUIREMENTS**

CFR(s): 493.1105(a)(4)

(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the technical consultant, the laboratory failed to retain proficiency testing records for at least two years for two (2023 VM-B and 2024 VM-B) of four proficiency testing events reviewed. Findings include: 1. A review of the laboratory's College of American Pathologists' proficiency testing records revealed a lack of graded results, attestation statements, results generated by the laboratory, and documented reviews of proficiency testing performance for 2023 VM-B and 2024 VM-C. 2. The surveyor requested the missing documentation on 5/12/25 at 10:17 am and was provided with the graded results printed from the proficiency testing provider's website, which lacked attestation statements, results generated by the laboratory, and documented reviews of proficiency testing performance. 3. An interview on 5/12/25 at 11:50 am with the technical consultant confirmed the lack of proficiency testing records for the events listed above.

**D5417**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**

CFR(s): 493.1252(d)

(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:

. Based on observation and interview with the technical consultant revealed the laboratory failed to ensure its potassium hydroxide (KOH) reagent used in performing KOH preparations had not exceeded expiration dates for one of three bottles observed. Findings include: 1. On 5/12/25 at 8:59 am, the surveyor observed a bottle of KOH

reagent near the microscope with the expiration date of 10/1/22. 2. An interview on 5/12/25 at 10:37 am with the technical consultant confirmed the bottle had exceeded its expiration date.

**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 technical consultant, the laboratory failed to accurately transmit patient test results for its Human Immunodeficiency Virus (HIV) testing for one (patient #2) of five HIV patient test records reviewed. Findings include: 1. A review of the laboratory's patient testing log revealed patient #2 received testing using the Alere Determine HIV 1/2 Antigen and Antibody Combo test kit on 4/23/25 with the following results: a. Antibody: Reactive b. Antigen: Nonreactive 2. A review of the test report for patient #2 revealed a section stating "Result: HIV 1/2 Ag/Ab Combo: positive" but did not specify whether the antigen or antibody portion of the test was positive. 3. An interview on 5/12/25 at 11:33 am with the technical consultant confirmed the test report did not specify whether the antigen or antibody portion of the test was positive for patient #2.