| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 23D2054540 | 03/22/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Wayne Health - Canfield And Tolan Park | 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.

| (X4) ID Prefix Tag | Summary Statement of Deficiencies |
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| **D2015** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(5)(6)<br><br>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview with Technical Consultant #2 (TC2), the laboratory failed to retain report forms used by the laboratory to record proficiency testing results and the attestation statement signed by the analyst and the laboratory director for at least 2 years for 1 (2nd Event 2022) of 3 proficiency testing events reviewed. Findings include: 1. A review of the laboratory's proficiency testing records revealed a lack of documentation of the College of American Pathologists' Proficiency Testing 2nd Event in 2022 for viral markers. 2. The surveyor requested documentation of the proficiency testing event documentation on 3/21/23 at 10:44 am and the report forms used by the laboratory to record proficiency testing results and the attestation statement signed by the analyst and the laboratory director were not made available. 3. Email correspondence on 3/22/23 at 1:46 pm with TC2 confirmed the laboratory had not retained report forms used by the laboratory to record proficiency testing results and the attestation statement signed by the analyst and the laboratory director for the 2nd event in 2022. ***This is a repeat deficiency from the 8/31/15, 9/17/19, and 9/22 /21 surveys.*** |

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| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview with Technical Consultant #2 (TC2), the laboratory failed to follow its competency assessment policy for testing personnel competency for 4 (Testing Personnel #2, 3, 7, and 8) of 8 testing personnel listed on Form CMS-209. Findings include: 1. A review of the laboratory's personnel competency records revealed the following testing personnel lacked competency assessments: a. TC2/Testing Personnel #8 had no record of competency assessments performed in 2022. b. Testing Personnel #2 with a start date of 10/13/21, had one competency assessment performed on 10/17/22. No documentation of competency assessments performed at least semiannually within the first year of testing. c. Testing Personnel #3 with a start date of November 2021, had one competency assessment performed on 10/19/22. No documentation of a second competency assessment performed at least semiannually within the first year of testing. d. Laboratory Director /Testing Personnel #7 had no record of competency assessments performed in 2022. 2. A review of the laboratory's "Quarterly QA Checklists" from September 2021 to February 2023 revealed one of the checklist criteria was, "Are all testing personnel evaluated at six months after beginning patient testing and then at least annually thereafter?" and each checklist had an "SH" for these criteria indicated as reviewed. 3. A review of the laboratory's "Wayne State University Physician Group STD Clinic Laboratory" policy revealed a section titled "Competency Assessment" that was blank. 4. An interview on 3/21/23 at 10:36 am with TC2 confirmed the testing personnel listed above did not have competency assessments performed at six months after beginning patient testing and then at least annually thereafter for the testing personnel listed above. ***This is a repeat deficiency from the 8/31/15 and 9/22/21 surveys.*** |
| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview with Technical Consultant #2 (TC2), the laboratory failed to verify its Wet Preparation and Potassium Hydroxide (KOH) Preparation testing at least twice annually for 1 (2022) of 2 years reviewed. Findings include: 1. A review of the laboratory's records revealed verification of accuracy testing for Wet Preparations and KOH Preparations was performed on 3/14/23 and 9 /21/21. 2. The surveyor requested verification of accuracy documentation for testing performed in 2022 on 3/21/23 at 10:42 am and it was not made available. 3. An interview on 3/21/23 at 10:42 am with TC2 confirmed the laboratory had not verified the accuracy of its Wet Preparation and KOH Preparation testing in 2022. ***This is a repeat deficiency from the 9/17/19 survey.*** |
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| **D5433** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(b)(1)<br><br>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview with Technical Consultant #2 (TC2), the laboratory failed to follow its policy for maintaining its pipette used in Alere HIV-1/2 Ag/Ab Combo testing for 20 (August 2021 to March 2023) of 21 months reviewed. Findings include: 1. A review of the laboratory's "STD Laboratory Equipment Maintenance" policy revealed a section titled "Pipettes" stating, "Pipettes will be calibrated at least once a year by Precision Biomedical Services. A maintenance log will be signed after maintenance has occurred." 2. A review of the laboratory's documentation for pipette maintenance revealed the most recent time service was performed on the pipette was 7/21/21. 3. An interview on 3/21/23 at 10:39 am with TC2 confirmed the laboratory had not performed annual maintenance for the pipette used in Alere HIV-1/2 Ag/Ab Combo testing at least annually. ***This is a repeat deficiency from the 9/17/19 survey.*** |
| **D6022** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>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 the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview with Technical Consultant #2 (TC2), the Laboratory Director failed to ensure the quality assessment program was maintained and identified failures in quality as they occurred when quality control was not performed for the Alere HIV-1/2 Ag/Ab Combo test kit for 1 (7/16/22) of 12 testing dates reviewed. Findings include: 1. A review of the laboratory's corrective action documentation revealed the patients indicated in the review performed on 3/17/23 were tested on 7/16/22 when quality control was not performed on the Alere HIV-1/2 Ag/Ab Combo test kit. A total of 7 patients were tested using this kit on 7/16/22. 2. A review of the laboratory's "Quarterly QA Checklists" revealed a section stating, "Check all QA/QC logs, ensure all required fields are completed (for example actual temperature, initials, dates, ranges, etc.). Were calibration/function checks performed and documented as needed on daily QC log (Example rotator)?" 3. A review of the laboratory's "Quarterly QA Checklists" from September 2021 to February 2023 revealed an "SH" next to each of the quality control log review sections, indicating quality control logs were reviewed. 4. An interview on 3/21/23 at 11:05 am with TC2 |

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| | confirmed the laboratory had identified the testing date when quality control had not been performed, the laboratory had performed corrective action for 5 of the 7 patients tested; the remainder had not been reached. The quarterly review of the quality control logs had not identified the errors as they occurred. ***This is a repeat deficiency from the 9/22/21 survey.*** |