Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2054540	09/17/2019
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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (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. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #2 (TP2), the laboratory failed to obtain attestation statements signed by the laboratory director and testing personnel for 4 (2019 G-A, 2018 G-C, 2018 G-B, 2018 G-A) of 6 testing events reviewed. Findings include: 1. A review of the College of American Pathologists' proficiency testing forms for syphilis serology testing revealed a lack of attestation statements for the following testing events: a. 2019 G-A b. 2018 G-C c. 2018 G-B d. 2018 G-A 2. An interview on 9/17/19 at 11:30 am with TP2 confirmed attestation statements were not signed by the laboratory director and testing personnel. **This is a repeat deficiency from the 8/31/15 survey**
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: . Based on record review and interview with the Office Manager, the laboratory failed to perform verification of accuracy for wet-mount preparation testing for 2 (September 2017 to September 2019) of 2 years. Findings include: 1. A record review revealed a lack of twice annual verification of accuracy for wet-mount preparation testing. 2. An interview on 9/17/19 at 1:27 pm with the Office Manager confirmed verification of accuracy of wet-mount preparation testing was not available.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to follow established general laboratory systems quality assessment policies and procedures for 2 (September 2017 to September 2019) of 2 years. Findings include: 1. A record review of the "Quality Assessment Manual for Rapid HIV Testing" procedure revealed a section stating, "The site coordinator must perform a review of test records and client charts on a quarterly basis to ensure that laboratory results are accurately transcribed into client charts." 2. On 9/17/19 at approximately 12:00 pm, the surveyor requested documentation of general laboratory systems quality assessment activities performed by the laboratory. 3. An interview on 9/17/19 at approximately 12:00 pm with TP1 confirmed documentation of general laboratory systems quality assessment activities were not available.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: . The laboratory failed to meet applicable analytic system requirements and correct identified problems. Findings include: 1. The laboratory failed to perform function checks on the pipette, centrifuge, microscope, and rotator. Refer to D5433. 2. The laboratory failed to establish the number, type and frequency of testing control materials used in syphilis serology testing. Refer to D5441. 3. The laboratory failed to perform quality control each day of syphilis serology testing and Human Immunodeficiency Virus (HIV) testing. Refer to D5449.
D5433	MAINTENANCE AND FUNCTION CHECKS

	CFR(s): 493.1254(b)(1) 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. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with Testing Personnel #2 (TP2), the laboratory failed to perform function checks on the pipette, centrifuge, microscope, and rotator for 1 (due March 2019) of 2 years. Findings include: 1. A tour of the laboratory on 9/17/19 at 8:54 am revealed the following equipment had past calibration expiration: b. Fisher brand Elite pipetter, last documented calibration 4/4 /17. c. Nikon Eclipse E100 microscope, expired March 2019. d. Clay Adams Nutator rotator, expired March 2019. 2. A review of the "STD Laboratory Equipment Maintenance" policy revealed the following equipment maintenance procedures: a. "Microscopes will receive maintenance once a year." b. "Pipettes will be calibrated at least once a year." c. "Centrifuge will receive maintenance once a year." 3. An interview on 9/17/19 at 9:07 am with TP2 confirmed the above mentioned maintenance was not completed annually according to laboratory policy.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on record review and interviews with Testing Personnel #1 (TP1) and Testing Personnel #2 (TP2), the laboratory failed to establish the number, type, and frequency of testing control materials used in syphilis serology testing for 2 (September 2017 to September 2019) of 2 years. Findings include: 1. A review of the "RPR Testing for Syphilis" procedure revealed a section titled "Quality Control" stating, "Controls with graded reactivity should be included in each test run to confirm optimal reactivity of the antigen. If control samples do not yield the expected response, the assay should be considered invalid and the assay repeated. If the repeat assay does not elicit the expected results for the control samples, discontinue use of the kit and contact ASI Technical Services." 2. A review of the Arlington Scientific, INC ASI RPR Card Test package insert's "Quality Control" section states, "Quality control requirements must be performed in accordance with applicable local, state, and/or federal regulations or

	accreditation requirements and your laboratory's standard Quality Control Procedures." 3. In an interview on 9/17/19 at 11:18 am, TP2 stated syphilis serology quality control testing was performed weekly. 4. An interview on 9/17/19 at 12:23 pm with TP1 confirmed the "RPR Testing for Syphilis" procedure did not contain the number, type, and frequency of testing control materials.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . A. Based on record review and interview with Testing Personnel #2 (TP2), the laboratory failed to perform quality control each day of syphilis serology testing for 6 (patients number 1-6) of 6 patients reviewed. Findings include: 1. A record review of the Arlington Scientific, INC ASI RPR Card Test kit package insert revealed a section titled "Quality Control" stating, "quality control requirements must be performed in accordance with applicable local, state, and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control Procedures." 2. A patient chart review and "Syphilis Serology Quality Control RPR" log review revealed the following patients had syphilis serology testing performed on days quality control testing had not been documented: a. Patient #1 on 8/2/19 b. Patient #2 on 6/27/19 c. Patient #3 on 3/15/19 d. Patient #4 on 8/21/18 e. Patient #5 on 3/29/18 f. Patient #6 on 11/30/17 3. In an interview on 9/17/19 at 11:18 am, TP2 stated syphilis serology rapid plasma reagin (RPR) quality control was performed weekly. 4. An interview on 9/17 /19 at 11:18 am with TP2 confirmed syphilis serology RPR quality control testing was not performed each day of patient testing. B. Based on record review and interview with Testing Personnel #2 (TP2), the laboratory failed to perform quality control testing each day of Human Immunodeficiency Virus (HIV) testing for 4 (4/12/19, 9/10 /19, 9/11/19, and 9/12/19) of 260 days reviewed. Findings include: 1. A record review of the laboratory's "HIV Rapid Testing: Alere Determine HIV- 1/2 Ag/Ab Combo" procedure revealed a section stating, "Waived testing for whole blood fingerstick samples only. (Venipuncture whole blood, serum, and plasma samples require a Moderate Complexity designation and, therefore, cannot be used in testing sites having only a waived designation)." 2. A record review of the laboratory's "HIV Rapid Testing: Alere Determine HIV- 1/2 Ag/Ab Combo" procedure revealed a section titled "Frequency of Controls" stating, "For sites testing more than 25 clients per day (high-volume), controls are to be run once each day of testing. For all other sites, including sites testing fewer than 25 clients per day (low-volume), controls can be run once per week when testing is performed." 3. A record review of the "Alere Determine HIV- 1/2 Ag/Ab Combo" package insert revealed a section stating, "CLIA Complexity: Moderate For Venous Whole Blood, Serum, and Plasma Samples." 4. A record review of HIV quality control testing logs and HIV patient testing logs revealed quality control was not recorded for the following days: a. 9/10/19, 4 patients tested b. 9/11/19, 4 patients tested c. 9/12/19, 6 patients tested d. 4/12/19, 4 patients tested 5. In an interview on 9/17/19 at 9:51 am, TP2 stated venipuncture whole blood specimens were tested. 6. An interview on 9/17/19 at 10:54 am with TP2 confirmed quality control had not been performed for the days listed above.

D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on record review and interview with Testing Personnel #1 (TP1), the laboratory director failed to evaluate syphilis serology proficiency testing results for 4 (2019 G-A, 2018 G-C, 2018 G-B, and 2018 G-A) of 6 testing events reviewed. Findings include: 1. A review of the College of American Pathologists' syphilis serology proficiency testing results revealed a lack of documented review by the laboratory director. 2. A review of the "Proficiency Testing" section of the "Quality Assessment Manual for Rapid HIV Testing" stated, "All testing personnel need to review the PT scoring and sign an acknowledgement of review." 3. An interview on 9/17/19 at 11:31 am with TP1 confirmed the lack of documented review of proficiency testing results by the laboratory director.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1 (TP1), the laboratory director failed to specify, in writing, the job responsibilities and duties for the laboratory director, clinical consultant, technical consultant, and testing personnel and for 9 of 9 personnel noted on the CMS-209 form. Findings include: 1. A review of personnel records revealed a lack of documentation of job responsibilities for the following personnel holding positions in the laboratory: a. The Laboratory Director also functioning as the Technical Consultant and Testing Personnel #8 b. Clinical Consultant c. Testing Personnel #1 d. Testing Personnel #2 e. Testing Personnel #3 f. Testing Personnel #4 g. Testing Personnel #5 h. Testing Personnel #6 i. Testing Personnel #7 2. An interview on 9/17/19 at 12:23 pm with TP1 confirmed the laboratory director had not specified the job responsibilities for laboratory personnel listed on the CMS-209.

D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: . Based on record review and interviews with Testing Personnel #2 and the Office Manager, the Technical Consultant failed to evaluate the competency of testing personnel for 2 (September 2017 to September 2019) of 2 years. Findings include: 1. A review of personnel competency records revealed the following testing personnel were missing competency records a. Testing Personnel #1 competency records not available b. Testing Personnel #2 semiannual competency not available c. Testing Personnel #3 competency records from 2018 not available d. Testing Personnel #4 competency records not available e. Testing Personnel #5 competency records not available f. Testing Personnel #7 competency records not available g. Testing Personnel #8 competency records not available 2. An interview on 9/17/19 at 10:57 am with Testing Personnel #2 confirmed competency records for the testing personnel listed above were not available.