Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2054540	09/22/2021
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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 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. This CONDITION is not met as evidenced by: . Based on a lack of documentation and interview with Technical Consultant #1 (TC1), the laboratory failed to enroll in an approved proficency testing program for Anti-Human Immunodeficiency Virus (Anti-HIV) testing for 2 (September 2019 to September 2021) of 2 years reviewed. Findings include: 1. A review of the laboratory's proficiency testing records revealed a lack of documentation of enrolling in an approved proficiency testing program for the laboratory's "Rapid HIV 1/2 Ag /Ab" testing listed on the test menu. 2. An interview on 9/22/21 at 9:02 am with TC1 confirmed the laboratory had not enrolled in an approved proficiency testing program for its HIV testing.
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 Technical Consultant #1 (TC1), the laboratory failed to maintain the attestation statement for 1 (2020 Event G-C) of 1 testing event reviewed. Findings include: 1. A review of the laboratory's College of American Pathologists' (CAP) proficiency testing records revealed a lack of attestation for the performance of Syphilis Serology testing in Event G-C of 2020. 2. An interview on 9/22/21 at 12:39 pm with TC1 confirmed the attestation for the event listed above was not available. ***This is a repeated deficiency from the 9/17/19 recertification survey.***
D5209	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 Technical Consultant #1 (TC1), the laboratory failed to assess testing personnel competency for 2 (Testing Personnel #2 and #3) of 5 testing personnel listed on the CMS-209 form. Findings include: 1. A review of the laboratory's competency assessment records revealed Testing Personnel #2 and #3 did not have competency assessments performed in 2020. 2. A review of the laboratory's "Quarterly QA Checklists" from 10/1/19 to 8/12/21 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 a "Y" for these criteria indicated as reviewed. 3. An interview on 9/23/21 at 9:16 am with TC1 confirmed the testing personnel listed above did not have competency assessments performed in 2020.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: . Based on record review and interviews, the laboratory failed to meet applicable preanalytic system requirements and correct identified problems. Findings include: 1.

	The laboratory failed to follow urine specimen labeling policies. Refer to D5311 A. 2. The laboratory failed to establish specimen labeling procedures for Wet Prep and Potassium Hydroxide (KOH) examinations Refer to D5311 B. 3. The laboratory failed to follow its specimen collection procedure for vaginal specimens. Refer to D5311 C.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: . A. Based on observation, record review, and interview with Testing Personnel #1, the laboratory failed to follow urine specimen labeling policies for 2 of 2 urine specimens observed. Findings include: 1. A review of the laboratory's "STD Clinic Laboratory" procedure revealed a section titled "ORDERS FOR LABORATORY TESTS" stating, "Specimens should be labeled by the staff member collecting the specimen at the time of collection." and "Patients self -collecting specimens must be given a urine container or swabs that are prelabeled with first and last name and birthday and specimen source." 2. The surveyor observed two urine cups with the patient labels on the lid and not on the specimen on 9/22/21 at 9:19 am. 3. An interview on 9/22/21 at 9:19 am with TP1 confirmed the specimens had not been labeled with the patient information. B. Based on observation, record review, and interview with Testing Personnel #4, the laboratory failed to establish specimen labeling procedures for Wet Prep and Potassium Hydroxide (KOH) examinations for one of two observations of Wet Prep and KOH examinations observed. Findings include: 1. A review of the laboratory's "Wet Prep" procedure revealed it did not mention the labeling of patient specimen slides. 2. The surveyor observed TP4 perform a Wet Prep and KOH examinations with unlabeled patient slides on 9/22/21 at 9:20 am. 3. An interview on 9/22/21 at 9:23 am with TP4 confirmed the slides did not have patient identifiers. C. Based on observation, record review, and interviews, the laboratory failed to follow its specimen collection procedure for vaginal specimens for one of two observations of Wet Prep and Potassium Hydroxide (KOH) examinations. Findings include: 1. The surveyor observed TP5 perform Wet Prep and KOH examinations on 9/22/21 at 10:42 am. 2. An interview on 9/22/21 at 10:42 am with TP5 revealed the specimen was collected by the patient. 3. A review of the laboratory's "Wet Prep" procedure revealed a section titled "Specimen Collection" stating, "Place approximately 0.5ml of 0.90% nonbacteriostatic normal saline in a small test tube (i.e.10x75mm). The saline must be at room temperature. Collect vaginal material on a swab by rubbing the vaginal wall or by collecting material from the posterior forices, and emulsify in saline." 4. An interview on 9/22/21 at 12:40 pm with Technical Consultant #1 confirmed the laboratory does not accept patient-collected Wet Prep and KOH examination specimens for testing.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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. This STANDARD is not met as evidenced by: . Based on record review and interview with Technical Consultant #1 (TC1), 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 and Rapid Plasmin Reagin (RPR) Syphilis testing for 8 (12/26/19, 11/5/20, 11/12/20, 1/6/21, 1/11/21, 1/20/21, 1 /21/21, and 2/12/21) of 18 testing dates reviewed. Findings include: 1. A review of the laboratory's corrective action documentation revealed the patients indicated in the review were tested on the following dates when quality control was not performed: a. 12/26/19, RPR quality control was not performed. b. 11/5/20, RPR quality control was not performed. c. 11/12/20, RPR quality control was not performed. d. 1/6/21, HIV quality control was not performed. e. 1/11/21, HIV quality control was not performed. f. 1/20/21, HIV quality control was not performed. g. 1/21/21, HIV quality control was not performed. h. 2/12/21, HIV quality control was not performed. 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 10/1/19 to 8/12/21 revealed a "Y" next to each of the quality control log review sections, indicating quality control logs were reviewed. 4. An interview on 9/22/21 at 11:24 am with TC1 confirmed the laboratory had identified 8 testing dates when quality control had not been performed, the laboratory had performed corrective action for patients tested "within this past week", and the quarterly review of the quality control logs had not identified the errors.