

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0661914	(X3) Date Survey Completed 07/23/2026
Name of Provider or Supplier City Of Milwaukee Hlth Dept	Street Address, City, State 841 N Broadway, Milwaukee, WI	
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
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 surveyor review of the laboratory's procedure manual and interview with the laboratory director, Staff A, the laboratory's one of one procedure for performing rapid plasma reagin (RPR) titers did not specify the requirement to document the value of the titer reactivity of the quality control material. Findings include: 1. Review of the control procedures section of the laboratory's RPR procedure did not specify the requirement to document the titer reactivity of the control material. 2. Interview with Staff A on July 23, 2026, at 4:00 PM confirmed the RPR procedure did not specify

	the requirement to document the titer reactivity of the control material. This is a repeat deficiency; D5403 was previously cited April 20, 2024, and May 11, 2022.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. This STANDARD is not met as evidenced by: Based on surveyor review of media quality control records and observation of media in the laboratory and interview with a laboratory supervisor (Staff D) and the laboratory director (Staff A), the laboratory did not document completion of quality control testing of four of four in-use batches of media reviewed. Findings include: 1. Review of 'Quality Control Record' forms for four media types showed the laboratory did not document quality control results for the current batch of the media. Media Date Prepared Sterility QC Growth QC Acetate Differential Agar Slants 5/6/26 results and date not documented results and date not documented Oxoid GC Base + Vitox (No Hemoglobin) 04/27/26 none none GN Broth (Hajna) 5/14/26 none none MacConkey Agar + Sorbitol 6/3/26 none none The reviewed records showed no evidence of supervisory review. 2. Observation of media in the laboratory refrigerator showed GN broth from the 5/14/26 batch, Acetate slants from the 5/6/26 batch, MacConkey Agar + Sorbitol from the 6/3/26 batch available for use. 3. Interview with Staff D on July 23, 2026, at 2:00 PM revealed the observed media in the laboratory refrigerator was available for use in patient testing and confirmed personnel should have completed quality control testing before placing the media in the laboratory refrigerator. 4. Interview with Staff A on July 23, 2026, at 2:45 PM confirmed the records did not show completion of quality control testing of the identified media types.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Item 1 Based on surveyor review of laboratory records and interview with a general supervisor, Staff B, the laboratory did not evaluate and define the relationship between test results on the test systems used for respiratory virology testing on a twice a year basis for the past two of two years. Findings include: 1. Review of laboratory records showed the laboratory performed respiratory virology testing on the Cepheid GeneXpert instrument, the Diasorin MAGPIX NxTAG system, and on the ABI 7500dx system using Centers for Disease Control (CDC) developed assays. Further review showed no evaluation of twice yearly comparison of test results across the

	three systems. 2. Interview with Staff B on July 22, 2026, at 2:10 PM confirmed the laboratory did not evaluate and define the relationship between test results on the respiratory viral testing systems on a twice a year basis for the past two of two years. Item 2 Based on surveyor review of laboratory records and interview with a general supervisor, Staff C, the laboratory did not evaluate and define the relationship between test results for the tests available on the Hologic APTIMA Panther analyzers on a twice a year basis for the past two of two years. Findings include: 1. Review of laboratory records showed the laboratory offered patient testing on its two Hologic APTIMA Panther analyzers for Mycoplasma genitalium, Trichomonas vaginalis, Neisseria gonorrhea, and Chlamydia trachomatis. Further review showed no evaluation of twice yearly comparison of test results between the two analyzers. 2. Interview with Staff C on July 23, 2026, at 9:00 AM confirmed the laboratory did not evaluate and define the relationship between the test results for tests available on both Hologic Panther analyzers on a twice a year basis for the past two of two years.
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 surveyor review of four of four test reports and interview with a general supervisor, Staff C, the test reports did not specify the name of the performing laboratory. Findings include: 1. Review of the test reports revealed the reports did not specify the performing laboratory for results from the Trichomonas vaginalis NAAT test, Mycoplasma genitalium NAAT test, Neisseria gonorrhea NAAT test, Chlamydia trachomatis NAAT test, and Hepatitis C quantitative NAAT test. 2. Interview with Staff C on July 23, 2026, at 9:45 AM confirmed the test reports did not indicate the name of the performing laboratory. This is a repeat deficiency; D5805 was previously cited May 11, 2022.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) (b)(8)(iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; This STANDARD is not met as evidenced by: Based on review of maintenance logs, the laboratory's individualized quality control plan (IQCP), and interview with a general supervisor, Staff B, the laboratory failed to document monthly review of quality control (QC) records and preventative maintenance records for the past twelve of twelve months for the Cepheid GeneXpert analyzer as part of the competency evaluation of testing personnel. Findings include: 1. Review of the laboratory's IQCP quality assessment (QA) plan for the GeneXpert

analyzer stated the laboratory performs daily review of internal QC and monthly review of external controls and instrument maintenance. 2. Review of preventative maintenance logs and quality control records for the Cepheid GeneXpert revealed no evidence the laboratory reviewed the records on a monthly basis. Further review of the logs revealed the laboratory failed to document quarterly maintenance for one quarter. 3. During an interview with Staff B on July 22, 2026, at 2:10 PM, Staff B revealed maintenance is reviewed annually when preparing for the IQCP review and confirmed the laboratory failed to review the maintenance and QC records at the frequency described in the IQCP QA plan.