Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0661914	04/26/2024
Name of Provider or Supplier	**Street Address, City, State**	
City Of Milwaukee Hlth Dept	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) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 laboratory procedures and the laboratory's plan of correction submitted in response to deficiencies cited at D5403 on May 11, 2022, and interview with a general supervisor (staff A), the laboratory did not correct one of two items cited at D5403 during the last survey. The procedure for Salmonella Typing did not specify the identity of the external quality control (QC) material, the criteria to determine acceptable quality control results, or the frequency of performing quality control for Salmonella typing antisera. Findings include: 1. Review of the "Salmonella Typing" standard operating procedure (SOP), last reviewed and signed by the CLIA

	laboratory director on December 27, 2023, revealed the procedure did not define QC requirements for the Salmonella antisera to include the identity of the QC material used, criteria to determine acceptable QC results or the frequency for performing QC. 2. The plan of correction submitted by the laboratory for survey event 536G completed on May 11, 2022, stated, "The laboratory is in process of drafting an updated Salmonella culture isolation, identification, and confirmation SOP detailing the process of what quality control strains to use for bi-annual QC and acceptable results by 08/31/2022". 3. Interview with staff A on April 26, 2024, at 2:00 PM confirmed the laboratory had not completed the revised procedure for Salmonella typing as stated in their last plan of correction and confirmed the procedure currently in place did not specify the identity of the quality controls (QC) used, the criteria to determine acceptable quality control results or the frequency of performing quality control for the salmonella antisera. This is a repeat deficiency previously cited on May 11, 2022.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory procedure manuals, and interview with a technical supervisor (Staff D) and a general supervisor (Staff C), the laboratory had not maintained copies of their discontinued procedures to include dates of discontinuance. The laboratory had not identified twelve of twelve discontinued procedures as discontinued and did not include a discontinued date with the procedures. Findings include: 1. Review of two laboratory procedure manuals showed the manuals included the following procedures. The individual procedures showed no evidence of discontinuation. GeneXpert RT-PCR (Real Time Polymerase Chain Reaction) assays (GeneXpert Dx) Procedure Manual. The manual included a table of contents showing the following five procedures: 1. IQCP (Individualized Quality Control Plan) GeneXpert assays 2. Xpert Clostridium difficile RT-PCR assay at MHDL 3. Xpert MTB/RIF (Mycobacterium Tuberculosis/Rifampin resistance) assay 4. Detection and identification of Bordetella (B.) pertussis, B. parapertusis, and B. holmesii by RT-PCR using ABI7500 5. Detection of Legionella (L.) spp. and L. pneumophila from clinical and environmental specimens by RT-PCR using ABI7500 Dx MHDL (Milwaukee Health Department Laboratory) Mycobacteriology Procedure Manual. The manual included a table of contents that listed eight procedures. The list below does not include procedures four, five and eight; the table showed the laboratory discontinued those procedures prior to the last survey. 1. Collection, transport, processing of specimens for detection of Mycobacterium spp. 2. Auromine-Rhodamine Fluorescence Stain for Acid Fast Bacilli 3. Acid Fast Staining protocol 6. AccuProbe Mycobacterium Identification 7. Procedure for handling mycobacterial aerosols 2. Review of other procedure manuals revealed two versions (Version 2 - effective May 5, 2022 and 2.1 - effective April 16, 2024) of a procedure for the Cepheid Xpert Xpress CoV-2/Flu/RSV plus Assay, Xpert Xpress CoV-2/ Flu plus Assay, or Xpert Xpress Cov-2 plus Assay using GeneXpert Dx System. Two versions were also available of a procedure for Maldi-Tof Testing (Version 1- effective March 14, 2022 and Version 1.1 -effective April 15, 2024). The earlier versions of these two procedures showed no evidence of discontinuation. 3. Interview with staff C on April 25, 2024, at 1:00 PM confirmed the laboratory discontinued the IQCP for the

	GeneXpert assays and had developed an individual IQCP for each assay, and confirmed the laboratory had not identified discontinued procedures or retained discontinued dates with the procedures. Interview with Staff D on April 26, 2024, at 4: 10 PM confirmed the laboratory discontinued all Mycobacteriology procedures. Email correspondence with Staff D on May 3, 2024, at 11:38 confirmed the laboratory had discontinued or revised the procedures in the GeneXpert real time PCR assays (GeneXpert Dx) Procedure Manual and confirmed the laboratory discontinued use of earlier versions of revised procedures when the current versions were put into use.
D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(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-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of control records for the RPR (Rapid Plasma Reagin) test and interview with a general supervisor (Staff B), the laboratory had not tested a control with a known titer when performing RPR titers on patient samples in the last four of four months. Findings include: 1. Review of control records from January through April 2024 for the RPR test showed no evidence the laboratory tested a control with a known titer when performing titers of positive patient samples. 2. Interview with Staff B on April 26, 2024, at 3:15 PM confirmed the laboratory did not test a control with a known titer when determining the titer of positive patient samples.
D5505	BACTERIOLOGY CFR(s): 493.1261(a)(3) (a) The laboratory must check the following for positive and negative reactivity using control organisms: (a)(3) When each batch (prepared in-house), lot number (commercially prepared), and shipment of antisera is prepared or opened, and once every 6 months thereafter. This STANDARD is not met as evidenced by: Based on surveyor review of quality control logs and the laboratory's plan of correction submitted in response to the deficiency cited at D5505 on May 11, 2022, and interview with a general supervisor (staff A), the laboratory did not perform Salmonella antisera quality control (QC) testing within six months for two of the three times testing was due from April 2022 through December 2023. Findings include: 1. Review of the Salmonella antisera QC records showed testing personnel performed QC testing in April and December 2022 and April and December 2023. 2. The laboratory's submitted plan of correction for the citation at D5505 for the 536G survey event completed on May 11, 2022, stated, "The general supervisor will ensure the new lot and shipment of commercially purchased antisera, and every six months thereafter, quality control is performed and documented." 3. Interview with staff A on April 26, 2024, at 2:00 PM confirmed the laboratory did not perform QC six months after

	completing the April control tests in 2022 or 2023. Staff A confirmed testing was due in October 2022 and 2023 and confirmed the corrective actions outlined in the previous plan of correction were not maintained. This is a repeat deficiency previously cited on May 11, 2022.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on surveyor review of maintenance logs and the laboratory's plan of correction submitted in response to deficiencies cited at D6072 on May 11, 2022, observation of analyzer records, and interview with a general supervisor (Staff A), testing personnel did not document all daily, weekly, monthly, and quarterly maintenance performed on the Cepheid GeneXpert test system in seven of seven months from September 2023 through March 2024. Findings include: 1. Review of the "GeneXpert System Maintenance Logs" revealed testing personnel documented weekly, monthly, and quarterly maintenance as shown below: September 2023 Weekly: September 1 Monthly or quarterly: none October 2023 Weekly: October 20 Monthly or quarterly: none November 2023 Weekly: November 22 Monthly or quarterly: none December 2023 Weekly: December 1, 21 and 28 Monthly none, Quarterly maintenance documented January 2024 Weekly: January 19 Monthly or quarterly: none February 2024 Weekly: February 2 and 9 Monthly or quarterly: none March 2024 Weekly: March 1 Monthly or quarterly: none 2. Observation of February 2024 testing records on the analyzer on April 26, 2024, at 2:15 PM and comparison with the maintenance logs showed personnel had not documented daily maintenance on February 9, 12, and 21 when performing patient testing and on February 23 when testing proficiency samples and controls. The analyzer records showed the laboratory performed one Mpox patient test on February 9, 2 SARS CoV-2 tests on February 12, and 1 SARS CoV-2 test on February 21. 3. The plan of correction submitted in response to the citation at D6072 on survey event 536G completed on May 11, 2022, stated, "The general supervisor will review the weekly maintenance record. The technical supervisor will work closely with the laboratory director to monitor that this deficiency practice doesn't happen again during the monthly review". 4. Interview with Staff A on April 26, 2024, at 2:30 PM confirmed testing personnel did not document all maintenance performed on the Cepheid GeneXpert test system and confirmed the laboratory had not maintained the corrective actions after the last survey. This is a repeat deficiency previously cited on May 11, 2022.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and

	493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on surveyor comparison of citations identified during this survey with the Centers for Medicare and Medicaid Services (CMS) Form 2567, Statement of Deficiencies from the May 10 - 11, 2022 survey, event 536G, and interview with a technical supervisor (Staff D), the laboratory director did not ensure the laboratory maintained the corrective actions needed to maintain compliance with regulations. Findings include: 1. The following citations are repeat deficiencies from prior surveys: Procedure Manual CFR:493.1251(b): Salmonella procedure was not revised after the last survey to include quality control requirements. See D5403. Bacteriology CFR:493.1261(a)(3): Salmonella typing antisera quality control testing was not completed every six months. See D5505. Testing Personnel Responsibilities CFR: 493.1425(b)(3): Testing personnel did not document required maintenance for the GeneXpert analyzer. See D6072. 2. Interview with Staff D on April 26, 2024, at 4:00 PM confirmed the laboratory did not sustain the corrective actions needed to maintain compliance.