

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0661914	(X3) Date Survey Completed 06/08/2018
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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and interview with the laboratory director, the current director has not approved, signed and dated the current procedures in mycology and virology. Findings include: 1. Review of the mycology procedures showed 20 of 20 procedures reviewed had not been approved, signed and dated by the current laboratory director. The manual includes a cover sheet for documenting procedure review; the current director has not signed the cover sheet. Review of the virology procedures showed no record of approval by the laboratory director. 2. Interview with the laboratory director on June 8, 2018 at 3:15 PM confirmed the procedures had not been signed and dated to show approval by the current director. Further interview revealed the current director has been in this role since January 2018. This is a repeat deficiency cited during the July 18, 2012 survey.</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of manufacturer's instructions and patient records, and</p>

interview with testing personnel, Cryptosporidium testing was performed on a specimen type that was not identified as acceptable in the manufacturer's instructions and had not been evaluated by the laboratory. Findings include: 1. Review of the manufacturer's instructions for the Merifluor Cryptosporidium assay showed the only identified acceptable specimen is preserved stool. 2. Review of testing records showed a Cryptosporidium assay performed on a duodenal aspirate collected June 1, 2018 on patient 1. 3. Interview with testing personnel, staff B, on June 7, 2018 at 3:00 PM confirmed Cryptosporidium testing was performed on a duodenal aspirate. Further interview confirmed the manufacturer did not identify duodenal aspirates as an acceptable specimen and that the laboratory had not evaluated the acceptability of the sample type to ensure adequate performance of the assay. This is a repeat deficiency previously cited on July 20, 2010.

D5431

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(2)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:
Based on surveyor review of function check records for the Gen-Probe Leader Luminometer, procedures, and manufacturer instructions, and interview with the general supervisor, the laboratory did not perform the SysCheck procedure as required. Findings include: 1. Review of documented maintenance and function check records for the Gen-Probe Leader Luminometer showed no record of use of SysCheck reagent as a calibration check of the luminometer in 2017. To date in 2018, there was only one recorded run in March. 2. Review of the manufacturer's instructions and laboratory procedures show the SysCheck reagent should be run every two weeks as a calibration check on the Leader. 3. Interview with the general supervisor, staff A, on June 8, 2018 at 1:45 PM confirmed the laboratory had no documentation to show SysCheck function checks were performed as required in 2017 and 2018.

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 surveyor review of procedures and interview with the general supervisor, the procedures do not define the number, type and frequency of control material to be

tested for the germ tube procedure. Findings include: 1. Review of the germ tube procedure in the mycology manual shows the procedure includes the following statement, "the medium used and incubation conditions must be monitored with appropriate controls to insure performance." The number, type and frequency of control testing required is not defined in the procedure. 2. Interview with the general supervisor on June 8, 2018 at 9:00 AM confirmed the procedure does not specify the number, type, or frequency of controls.

D5789

TEST RECORDS
CFR(s): 493.1283(b)

Records of patient testing including, if applicable, instrument printouts, must be retained.

This STANDARD is not met as evidenced by:
Based on surveyor review of the test records for Blastomyces dermatitidis and Coccidioides immitis from the Gen-Probe Leader analyzer and interview with the general supervisor, the laboratory did not retain test record printouts for 20 patient samples tested between July 1, 2016 and April 20, 2018. Findings include: 1. Review of records for the Gen-Probe Leader analyzer showed instrument printouts were not available for patient testing between July 2016 and April 2018. No records were available to show what dates the analyzer was used for patient testing. 2. Interview with the general supervisor, staff A, on June 8, 2018 at 9:00 AM confirmed the analyzer printouts were not retained.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Item 1 Based on surveyor review of quality control (QC) records and procedures for the GeneXpert Mycobacterium tuberculosis complex test, and interview with the general supervisor, the laboratory director did not ensure the QC program was established to meet regulatory requirements. Findings include: 1. Review of QC records for the GeneXpert Mycobacterium tuberculosis complex test show external QC performed when a new lot or shipment was put into use. External QC results are not available for each day of patient testing. 2. Procedures for the GeneXpert included a manufacturer's Risk Assessment for an IQCP (Individualized Quality Control Plan) for the Mycobacterium tuberculosis complex test. A Quality Control Plan and Quality Assessment Plan for the IQCP were not present. The procedures do not specify the type, number and frequency of testing external controls. 3. Interview with the general supervisor, Staff A, on June 8, 2018 at 1:00 PM confirmed external QC was not performed with each day of patient testing for Mycobacterium tuberculosis testing. Further interview confirmed an IQCP had not been completed for this test system.
Item 2 Based on surveyor review of test records for Blastomyces dermatitidis and Coccidioides immitis performed with the Gen-Probe AccuProbe test and interview with the general supervisor, the director did not ensure the quality control program was maintained as no quality control test records were available from July 2016

through April 2018. Findings include: 1. Review of test records for Blastomyces dermatitidis and Coccidioides immitis revealed no records of quality control testing from July 2016 through April 2018. 2. Interview with the general supervisor, staff A, on June 8, 2018 at 9:00 AM confirmed the printouts from the analyzer that include the quality control results were not retained. Further interview confirmed no other records of quality control testing are available.