Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2118388	03/04/2024
Name of Provider or Supplier	**Street Address, City, State**	
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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: I. Based on review of the policy and procedure manuals and interview with the testing person (TP), the laboratory failed to have written policies and procedures for documenting the lot numbers of the extraction reagents, and quality control (QC) material used by the laboratory on the "UTM" worksheet. Findings: 1. Review of the procedure manual showed that there were no written procedures for keeping records of the lot numbers and expiration dates of the extraction reagents, and QC materials used on the QuantStudio 7 polymerase chain reaction (PCR) analyzer. 2. During the exit interview on 03/04/2024 at 3:05 PM, the TP confirmed that the laboratory's

	procedure manual failed to include written policies and procedures for maintaining the lot numbers and expiration dates of the extraction reagents, calibration and QC materials when they were put into use. II. Based on review of the policy and procedure manuals and interview with the TP, the laboratory failed to include written policies and procedures for amending a patient report. Findings: 1. Review of the procedure manual showed that there were no written procedures for amending a patient report. 2. During an interview on 03/04/2024 at 3:05 PM, the TP confirmed that the laboratory's procedure manual failed to include written policies and procedures for amending a patient report. III. Based on review of the "Wipe Test Procedure", record review, and interview with the TP, the laboratory failed to provide the wipe test form for recording the results of the monthly wipe test. Findings: 1. The "Wipe Test Procedure" reviewed during the survey refers to "Form Lab-01 F01" to document the monthly wipe test results. 2. The wipe test records that were reviewed were not documented on "Form Lab-01 F01" that was referred to in the "Wipe Test Procedure." The TP stated that they were not aware of the form for recording the results and the form was not available at the time of the survey. 3. During an interview on 03/04/2024 at 3:05 PM, the TP confirmed that the laboratory's procedure manual failed to include the "Form Lab-01 F01" for recording the results of the monthly wipe test.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: I. Based on review of the procedure, monthly maintenance forms, and the manufacturer's operator's manual and interview with the general supervisor (GS) and testing person (TP), the laboratory's maintenance procedure for the QuantStudio 7 Flex real-time polymerase chain reaction (PCR) system did not include the correct instrument model, did not match maintenance tasks listed on the maintenance log, and did not match the manufacturer's recommendations. Findings: 1. The procedure titled "Equipment Maintenance and Remedial Plan" (equipment procedure) stated "The laboratory will establish a maintenance schedule for instruments used in the laboratory" and listed maintenance tasks to be performed daily, weekly, monthly, annually, and as needed for the "12 K Quant Studio." The laboratory used a QuantStudio 7 Flex (QS7) not a QuantStudio 12K Flex real-time PCR system. 2. The daily, weekly, monthly, annual, and as needed tasks listed in the equipment procedure did not match exactly to the maintenance tasks listed on the "QS7 Maintenance Log." For example, the procedure stated to perform "Disk clean up and defragmentation" on a monthly basis, but this task was not listed on the QS7 Maintenance Log. The procedure also stated to "perform instrument self-test" on a weekly basis, but this task was listed in the "as needed" section of the QS7 Maintenance Log. 3. The frequency of the maintenance activities listed in the equipment procedure did not match the frequency recommended by the manufacturer. For example, the "QuantStudio 6 and 7 Flex Real-Time PCR Systems User Guide" (publication 4489821, revision B, 2022) stated "Semi-annually (every 6 months)" to "Perform an ROI calibration," "Perform a uniformity calibration," "Perform a dye calibration," and "Perform a normalization calibration," but the QS7 Maintenance Log had these items listed to be performed "Annually" and the procedure did not mention performing the dye calibration and

	listed the other items to be performed "Annually." 4. During the exit interview on 03/04/2024 at 3:45 PM, the GS and TP confirmed that the incorrect model of the PCR system was listed in the procedure and the maintenance tasks listed in the procedure didn't match exactly to the maintenance tasks listed on the QS7 Maintenance Log. II. Based on review of the maintenance logs and interview with the general supervisor (GS) and testing person (TP), the laboratory failed to document performance of the maintenance tasks for the QuantStudio 7 Flex (QS7) real-time polymerase chain reaction (PCR) system with the frequency listed on the maintenance logs in 3 of 7 months reviewed. Findings: 1. The laboratory used a "QS7 Maintenance Log" to document maintenance tasks to be performed daily, weekly, monthly, annually, and as needed on the QS7 real-time PCR system. 2. Maintenance logs from 08/2023-02/2024 were reviewed. 3. No monthly maintenance tasks were documented as performed in 09/2023, no weekly or monthly maintenance tasks were documented as performed in 12/2023, and the weekly tasks were only documented as performed for one week in 02/2024. 4. During the exit interview on 03/04/2024 at 3:45 PM, the GS and TP confirmed that maintenance tasks for the QS7 real-time PCR system were not documented with the frequency defined on the maintenance logs. III. Based on review of the procedure, review of maintenance logs, and interview with the general supervisor (GS) and testing person (TP), the laboratory's maintenance logs for the biological hood and centrifuges did not match the activities listed in the procedure and there was no maintenance log available to document maintenance activities for the magnetic particle processor. Findings: 1. The procedure titled "Equipment Maintenance and Remedial Plan" (equipment procedure) stated "The laboratory will establish a maintenance schedule for instruments used in the laboratory." 2. The section in the equipment procedure for "Centrifuges" listed maintenance tasks to be performed weekly, monthly, and annually. The maintenance logs for the centrifuges only listed weekly tasks that did not match exactly to what was stated in the equipment procedure. For example, the equipment procedure stated that weekly "Centrifuges are cleaned and disinfected," "are inspected for broken or loose parts," and "Grease stainless steel post/pivots if indicated", but the weekly tasks listed on the maintenance logs were "Check: rotor (remove to clean)" and "Clean with EtOh: keypad, wipe inside, rotor." 3. The section in the equipment procedure for "Fume hoods" stated "Fume hoods should be wiped out after each use a 70% methanol solution." The "BioHood" maintenance log listed two weekly tasks to be performed: 1) "Check: air flow, UV, filter" and 2) "Clean: work space use UV for 10" /sash /walls." 4. The section in the equipment procedure for the "King Fisher" instrument listed two weekly maintenance activities and identified the instrument as the "KingFisher Flex." The laboratory used a KingFisher Duo Prime magnetic particle processor not a KingFisher Flex instrument. The laboratory did not have a log template to document the maintenance activities performed on the KingFisher Duo Prime magnetic particle processor. 5. During the exit interview on 03/04/2024 at 3:45 PM, the GS and TP confirmed that the maintenance tasks listed in the equipment procedure for the centrifuges and biological hood did not match the tasks listed on the maintenance logs, that the equipment procedure listed the incorrect KingFisher model in use, and that there were no logs to document maintenance activities performed for the KingFisher Duo Prime magnetic particle processor.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.

	This STANDARD is not met as evidenced by: Based on review of temperature records and interview with the testing person (TP), the laboratory failed to document corrective actions when room temperature and humidity were out of acceptable range in 6 of 7 months reviewed. Findings: 1. The procedure titled "Temperature and Humidity Checks" stated "Each day the temperature and humidity will be recorded for each area" and "If there is a variance from the acceptable range, it must be reported to a supervisor/member of the management team and actions taken to bring the temperature within an acceptable range." 2. The laboratory recorded room temperature and humidity on a single "Temperature/Humidity Log" which included the acceptable ranges for each. 3. Temperature logs were reviewed from 08/2023-02/2024. 4. Room temperature was documented as out of acceptable range for 3 of 30 days recorded in 09/2023, 6 of 31 days recorded in 10/2023, 6 of 30 days recorded in 11/2023, 3 of 31 days recorded in 12/2023, 16 of 31 days recorded in 01/2024, and 11 of 29 days recorded in 02/2024. 5. Humidity was documented as out of acceptable range for 5 of 30 days recorded in 11 /2023, 11 of 31 days recorded in 01/2024, and 11 of 29 days recorded in 02/2024 6. There were no corrective actions documented for any of the out-of-range values listed above. 7. During the exit interview on 03/04/2024 at 3:45 PM, the TP confirmed that corrective actions were not documented when temperature and humidity values were found to be out of acceptable range.
D5805	TEST REPORT CFR(s): 493.1291(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 review of final reports and interview with the testing person (TP), the laboratory failed to ensure that the final test report identified what organisms were being tested and interpretative information for the "Units", "Flag", and "Reference" columns listed on the final report for Urinary Tract Microbiota (UTM) Deoxyribonucleic acid (DNA) results. Findings: 1. Review of a final test report for a negative patient listed the "Test Information" as "UTM with Antibiotic Resistance" and an alphanumeric value for the diagnosis codes. The organisms and antibiotic resistance genes tested in the "UTM with Antibiotic Resistance" test panel were not identified in the report. The report failed to clearly identify that the organisms in the UTM panel were not detected and therefore negative. 2. Review of a final test report for a positive patient listed the "Test Information" as "UTM with Antibiotic Resistance" and an alphanumeric value for the diagnosis codes. The organisms and antibiotic resistance genes that were listed indicated the presence as "Detected" and the other organisms and antibiotic resistance genes on the panel were not listed. The section on the final report for "Units", "Flag", and "Reference" did not have any information for the evaluation of the results. 3. During the survey on 03/04/2024 at 3:

	00 PM, the TP confirmed that the negative and positive patient reports failed to include any interpretative information for the "Units", "Flag", and "Reference" columns listed on the final report.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment 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: Based on review of the quality assessment (QA) plan, and interview with the testing person (TP), the laboratory director (LD) failed to ensure that the established QA plan clearly defined which proficiency testing (PT) program the laboratory was using. Findings: 1. The QA plan states that each section is enrolled in a CMS-approved PT program for all tests performed. The QA plan does not indicate which PT program the laboratory has enrolled with on an annual basis. 2. During the exit interview on 03/04 /2024 at 3:15 PM, the TP confirmed that the QA plan did not indicate which PT program the laboratory has enrolled with on an annual basis.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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 review of initial training records, laboratory records, and interview with the testing person (TP) and technical supervisor (TS), the TS failed to ensure that the competency records included documentation showing that the TS had reviewed the test results reported prior to the completion of the TP competency evaluation. Findings: 1. The laboratory started reporting patient test results in August 2023. The initial training records show that the TP was not signed for as having been trained until 10/18/2023. 2. When interviewed the TP stated that they had been reporting patient test results since August 2023. The TS stated that all the instrument worksheets from the patient runs from August and September 2023 had been reviewed and approved by the TS. The records that were available at the time of the survey failed to include a documented review by the TS showing that the instrument worksheets had been reviewed and acceptable prior to releasing patient test results. 3. During the exit interview on 03/04/2024 at 3:15 PM, the TP and TS confirmed that the competency records failed to include a documented review of instrument worksheets prior to the competition of the competency of the TP on 10/18/2023.