Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2198785	07/14/2022
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review, the laboratory did not maintain proficiency testing attestation statements for testing personnel. Findings: 1. Proficiency testing attestation statements were not signed by the testing person(s) for the 2022 API (proficiency test provider) second event (UTI panel).
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: I. Based on record review the laboratory did not evaluate unsuccessful proficiency test (PT) results (individual proficiency test failures) for bacteriology. Findings: 1. The laboratory performs proficiency testing for molecular UTI bacteria/yeast testing; 2. PT Event 032521 split sample molecular testing. The laboratory passed the overall test event, but did not investigate test results that were unacceptable for sample U121 and sample U221; and 3. The laboratory did not detect the bacteria E. coli that was present in sample U121, and did not detect VRE VAN B (vancomycin resistant enterococcus) present in sample U221. The laboratory did not investigate the cause of the unsuccessful performance and determine if patient testing may have been affected. 4.

	There was no explanation or investigation into these unsatisfactory results and no determination if patient results around this time may have been affected. II. Based on record review, the laboratory did not have the directors evaluations for proficiency test events 62221 and 91321 (split samples). Findings: 1. The laboratory performed the split sampling for proficiency testing of molecular microbiology testing; 2. The laboratory did not have the test results (summary of acceptable performance) and scores provided by the proficiency test provider for each sample tested; and 3. The laboratory did not have records showing the director's review for either proficiency test event.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on record review, the laboratory did not take corrective action when the refrigerator temperature reading did not meet the laboratory's criteria for acceptability. Findings: 1. The acceptable temperature for the refrigerator is 39 to 46 degrees Fahrenheit (F); 2. On May 2, 2022 the temperature reading was 38 F, May 9, 2022 the reading was 37 F, May 10, 2022 the reading was 32 F, May 11, 2022 the reading was 37, May 14, 2022 the reading was 52 F. Corrective actions were not taken for these readings and no temperature rechecks were made after correction; 3. Humidity recordings were not documented for June, May, April and March of 2022; and 4. The laboratory did not have refrigerator temperature recordings for February 2022.
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 review of quality control records for the UTI molecular panel, the laboratory did not have quality control records for the week between October 11, 2021 and October 25, 2021, and the week between November 15, 2021 and November 29, 2021. Findings: 1. The laboratory had an Internal quality control plan (IQCP) for the

	UTI molecular panel used to detect, identify and provide susceptibility information for bacteria and yeast. According to the IQCP weekly quality control (QC) checks for positive and negative reactivity are performed to ensure the accurate and reliable testing of patient specimens; 2. The laboratory did not perform the weekly quality control checks for the week between October 11, 2021 and October 25, 2021, and the week between November 15, 2021 and November 29, 2021. The quality control checks for these two weeks was not recorded on the Molecular UTI Weekly QC Worksheet; and 3. The laboratory documents evaluation of weekly quality control checks for the molecular testing on weekly quality control worksheets that are used to interpret the results of the quality control checks as pass or fail. The January 2022 worksheets were missing and the only worksheet present for February 2022 was on the 28th, there were no worksheets for the first 2 weeks in March 2022, and there were no April 2022 worksheets (patient testing was reviewed for April 2022 and 66 patients were tested that month on April 1, 4, 5, 20, 21, 22 and 25).
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 record review, the laboratory did not document corrective actions when patient test findings did not the agree with the results reported for patient tests. Findings: 1. The laboratory reported "no sigs" (no laboratory description available for this finding) for patient specimen GT-28, but reported enterococcus sp. detected, the laboratory did not document any further reviews or corrective actions; 2. The laboratory reported that the plate for patient specimen GFW-28 was mislabeled, but corrective actions were not documented and reviewed by the director to ensure corrective actions prevent the problem from recurring; and 3. The laboratory did not report sulfonamide resistance for patient specimen BA-1 and also reported saprophyticus even though the test results reported it as not detected. There was no investigation for the discrepancy.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory staff, the laboratory did not perform or have written procedures to perform a look back of molecular microbiology test runs when a weekly quality control failure occurred. Findings: 1. The laboratory written procedures did not adequately define how to identify and document a quality

	control failure, the corrective actions taken to resolve the failure and to perform a look back for all test runs from the previous week to determine if any patients for the previous week were at risk due to the failure; 2. Since quality control testing is performed weekly, the laboratory must review all test runs from the previous week as it does not know when the analyzer stopped producing accurate test results (since external quality control is not performed every day of testing). The review must determine if any patients were at risk from inaccurate test results and perform corrective actions for any patients identified at risk; 3. This was confirmed during interview with laboratory staff during the afternoon of the survey; 4. On May12, 2021 it was reported that all positive quality control did not amplify and lab "will rerun". On May 13, 2021 it was reported that there was little amplification and "will rerun", on May 14, 2021 it was reported that the positive control was negative and will "rerun", on May 17, 2021 it was reported that there was no positive quality control, "will rerun". There was no investigation identifying the cause of the problem, corrective action was not documented and a look back was not performed and the laboratory failed to identify any patients that may have been put at risk for the previous week. A look back (to the last acceptable quality control) is required since the quality control failure not only affects that day of testing, but also all testing from the previous week, since quality control testing is only performed weekly; and 5. On July 29, 2021 and August 9, 2021 quality control failed. For either day of testing there was no investigation identifying the cause of the problem, corrective action was not documented and a look back was not performed and the laboratory failed to identify any patients that may have been put at risk for the previous week. A look back (to the last acceptable quality control) is required since the quality control failure not only affects that day of testing, but also all testing from the previous week, since quality control testing is only performed weekly.
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 record review, the laboratory director did not ensure that quality assurance procedures were maintained. Findings: 1. The laboratory had a written procedure (see quality assurance manual) to complete a checklist for proficiency testing samples. The checklist was to document the receipt and reporting of proficiency test results; 2. The checklist had not been used for proficiency testing performed in 2021 or 2022; 3. The laboratory director did not ensure that staff perform and document and report to the director all corrective actions necessary when quality control failures occur and ensure that look backs are performed to identify patients at risk when a quality control failure occurs. See D5783 for findings; and 4. The laboratory director did not periodically review the laboratory's individualized quality control plan to ensure that it is followed by staff, provides accurate and reliable test results and staff understand and follow the plan including how to identify, report to the lab director, and provide corrective action to quality control failures including performing look backs to ensure patient testing from the previous week were not affected when a quality control failure occurs.