

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0694263	(X3) Date Survey Completed 04/25/2023
Name of Provider or Supplier Harne Song & Woo Md Pa	Street Address, City, State 2007 Rock Spring Rd, Forest Hill, MD	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing and interview with laboratory staff, the laboratory did not check the accuracy of the molecular bacteriology and mycology testing at least two times each year. Findings: 1. The laboratory performs molecular bacteriology and mycology testing and during interview with laboratory staff the afternoon of the day of survey, participated in a proficiency testing program that checked the accuracy of the testing one time each year; and 2. The laboratory did not check the accuracy a second time each year (by testing blind samples or split samples or enrollment in a secondary proficiency testing program).</p>
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory proficiency testing records and interview, the laboratory did not review the proficiency test providers evaluation of the laboratory's proficiency test performance for molecular bacteriology and mycology testing. Findings: 1. The proficiency test provider did not provide the laboratory with an evaluation of it's test performance, but according to testing staff (during interview the afternoon of the survey) the proficiency test provider would notify the laboratory if it's performance was unacceptable and did not provide a record of the laboratory's</p>

performance; and 2. The proficiency test provider did not provide a result for each unknown sample tested and whether the laboratory passed or failed for each analyte it reported to the provider.

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 review of the laboratory room temperature and room humidity records and interview, the laboratory did not define the acceptable room temperature limits and did not define the acceptable humidity limits for performance of the molecular bacteriology and mycology testing. Findings: 1. The acceptable ranges for the room temperature and humidity where the molecular testing was performed was not documented on the daily temperature and humidity written worksheet and was not defined on the laboratory written procedure; and 2, This was confirmed during interview with the testing person the afternoon of the day of survey.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
Based on review of the laboratory test records and interview, the laboratory did not establish lot numbers and expiration dates for reagents used for bacteriology and mycology molecular testing. Findings: 1. The expiration dates for the external quality control reagents (positive and negative) and the test plates were not assigned an expiration date on their packaging and the laboratory did not have procedures to assign and document expiration dates for the external quality control reagents and test plates; 2. The laboratory did not document the lot number of the external quality control reagents (positive and negative) used for molecular testing. 3. This was confirmed during interview with the testing person the afternoon of the day of survey.

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:

A. Based on review of the laboratory centrifuge maintenance records for performance of the molecular bacteriology and mycology testing, the laboratory did not perform calibration checks to ensure that the centrifuge's relative centrifugal force (RCF) met the manufacturer's requirements for molecular testing. Findings: 1. The laboratory did not have documentation showing that the centrifuge's RCF was periodically checked as required by the manufacturer to ensure that it met the requirements for the molecular testing; and 2, This was confirmed during interview with the testing person the afternoon of the day of survey.

B. Based on review of the laboratory pipette maintenance records for performance of the molecular bacteriology and mycology testing, the laboratory did not perform calibration checks to ensure that the pipette delivery volume met the manufacturer's requirements for molecular testing. Findings: 1. The laboratory did not have documentation showing that the pipettes were periodically checked as required by the manufacturer to ensure that it met the requirements for the molecular testing; and 2, This was confirmed during interview with the testing person the afternoon of the day of survey.

C. Based on review of the laboratory calibration and tuning records for the analyzer (Quantstudio) used for molecular bacteriology and mycology testing, the laboratory did not perform calibration and tuning checks every two years as required by the manufacturer. Findings: 1. The laboratory did not have documentation showing that the analyzer was calibrated and tuned within the previous two years as required by the manufacturer to ensure that it met the requirements for the molecular testing; and 2, This was confirmed during interview with the testing person the afternoon of the day of survey.

D6086

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

This STANDARD is not met as evidenced by:

Based on review of the laboratory records and interview, the laboratory director did not ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the bacteriology and mycology molecular testing using UTI test plates and specimens obtained from rectal swabs (not urine specimens as indicated by the manufacturer). Findings: 1. The laboratory did not have written approval of the laboratory director's review of validation data to perform molecular testing from patient rectal swabs using UTI plates intended for urine specimens; 2. The laboratory director did not approve validation procedures and test results to verify the accuracy and precision of testing rectal swabs using UTI plates intended for urine samples for patient testing. 3, This was confirmed during interview with the testing person the afternoon of the day of survey.

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 molecular UTI weekly quality control records and interview, the laboratory director did not ensure that the quality control records were reviewed, signed and dated as indicated on the 2023 records showing review of the quality control record. Findings: 1. The quality control records have a place to document review of the record, but in 2023 the molecular UTI weekly quality control worksheet was not signed and dated where indicated to show review; and 2, This was confirmed during interview with the testing person the afternoon of the day of survey.

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 competency checks performed for testing staff, the laboratory director acting as the technical supervisor for the bacteriology and mycology molecular testing did not perform and document annual competency checks for testing staff. Findings: 1. The laboratory did not have documentation showing that testing staff were evaluated by the technical supervisor for annual competency checks that includes staff competency for performing preventive maintenance, performing quality control testing, performing patient testing and reporting test results for 2022; and 2, This was confirmed during interview with the testing person the afternoon of the day of survey.