

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0220849	(X3) Date Survey Completed 07/24/2023
Name of Provider or Supplier Meritus Urology	Street Address, City, State 11110 Medical Campus Rd Ste #228, Hagerstown, 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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the policy and procedure manuals, laboratory records, and interview with the testing person (TP), the laboratory's policy and procedure manuals failed to include written instructions for all activities that the TP performs. Findings: 1. According to the TP each patient and quality control (QC) run is given an identification (ID) number (#) that includes the year, month, date, and additional information depending on the test being performed. The instructions for labeling the run were not included in the procedure manual. 2. During the survey on 07/24/2023 at</p>

1:30 PM, the TP confirmed that the policy and procedure manual failed to contain written instructions assigning an ID# to each patient and QC run when performing testing.

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 policy and procedure manuals, "Weekly QC[quality control] control Information", "Molecular UTI [urinary tract infection] Weekly QC Worksheet" worksheets, and interview with the testing person (TP), the laboratory's procedure manual failed to include the expiration date of the patient plate, positive QC and negative QC materials used for patient testing. Findings: 1. The "Weekly QC control Information" and "Molecular UTI Weekly QC Worksheet" worksheets from March 2022 to July 2023 were reviewed. The records did not include the expiration dates of the patient plate, positive QC and negative QC materials used for patient testing. The TP confirmed that the expiration date was not recorded on the worksheet nor any other worksheet used in the laboratory. 2. During the survey on 07/24/2023 at 1:30 PM, the TP confirmed that the policy and procedure manuals and the worksheets listed above failed to include the expiration date of the patient plate, positive QC and negative QC materials used for patient testing to ensure that none of the materials were used past the manufacturers expiration date.

D6091

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

This STANDARD is not met as evidenced by:

Based on review of the urinary tract infection (UTI) proficiency testing (PT) records and interview with the testing person (TP), the laboratory director failed to investigate the PT failures and implement a corrective action plan for unacceptable PT testing results. Findings: 1. The American Proficiency Institute (API) PT records for the second and third microbiology events in 2022 showed the following results: a) API 2022-2nd event, specimen UTI-03, the expected result was "Not Detected" and the lab reported "Detected" for "Proteus mirabilis." The lab had a 50% score for this challenge. b) API 2022-2nd event, specimen UTI-03 received a "Not Graded" score for two of nine molecular resistance gene challenges and UTI-04 received a "Not Graded" score for nine of nine molecular resistance gene challenges. c) API 2022-3rd event, specimen UTI-05, the expected result was "Not Detected" and the lab reported "Detected" for "Citrobacter koseri" and "Enterobacter cloacae." The lab had a 50% score for each challenge. d) API 2022-3rd event, specimen UTI-05 received a "Not Graded" score for nine of nine of the molecular resistance gene challenges and UTI-06 received a "Not Graded" for two of nine molecular resistance gene challenges in urine. 2. The TP stated that there were no investigations of the PT failures listed

above. 3. During the survey on 07/24/2023 at 1:30 PM, the TP confirmed that the PT failures had not been investigated and corrective actions implemented to prevent reoccurrence of the failure.

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 policy and procedure manuals, quality assurance (QA) records, and interview with the testing person (TP), the laboratory director (LD) failed to ensure that the established quality assurance (QA) procedures were implemented to monitor the overall operation of the laboratory. Findings: 1. The QA procedure requires the technical supervisor (TS) or qualified designee "will review and sign off on the temperature and humidity logs", "will review and signoff that the laboratory duties have been completed", and "Quality control run logs will be reviewed by the technical supervisor or qualified designee." According to the TP the documents were emailed to the TS and there was not response letting the TP know that the records had been reviewed and found acceptable or needed investigation. After three months the TP went to the LD and asked what should be done. The LD started performing the TS duties and responsibilities and the QA procedure was not updated to reflect the changes. 2. The QA procedure requires the TS "will review the proficiency testing records for completion." The laboratory had proficiency testing (PT) failures during the second and third events in 2022 and there was no documented investigation of the failures. See Tag D6091 for details. 3. The QA procedure requires the TS to perform the "Competency Assessment- Testing personnel" "Six months and one year after initial training, annually thereafter." According to the TP there were no training records available showing any of the evaluations are required by the TS and the LD had not signed off on any training or evaluations. 4. The QA procedures require the TS or LD to perform a "Result Auditing" annually. According to the TP there were no "Result Auditing" documents from 2022 and 2023. 5. During the survey on 07/24 /2023 at 1:30 PM, the TP confirmed that the TS duties and responsibilities and the QA procedure was not updated to reflect the changes, PT failures were not investigated, initial training and evaluations were not documented, and the "Result Auditing" was not performed as required.

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 a review of laboratory records for the Qiagen QuantStudio3 (urine

polymerase chain reaction (PCR)) analyzers, and interview with the testing person (TP), the technical supervisor (TS) failed to provide documentation of the initial training of the testing person (TP). Findings: 1. According to the TP the manufacturer provided training through Precision Microbio. The trainer came to the office to train the TP. The TP stated that the training was to last for three days. The trainer was only at the office to provide training for one day. 2. The TS failed to ensure that the TP had the proper training 3. The TP has been working in the lab for 18 months and there are no records showing the initial training, six-month evaluation, and annual evaluation. 4. During the survey on 07/24/2023 at 1:30 PM the TP confirmed that the trainer from Precision Microbio had not provided and documented the required three days of training to ensure the initial competency of the current TP and the required six-month and annual evaluation.