

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2224733	(X3) Date Survey Completed 08/26/2026
Name of Provider or Supplier University Urology Associates	Street Address, City, State 490 Hwy 530, Manchester, NJ	
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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: A) Based on surveyor review of the PT records and interview with the General Supervisor (GS), the laboratory failed to verify the accuracy of Molecular resistance Genes - Urine results obtained from the API for the Microbiology 2nd event 2025. The findings include: 1. The laboratory received a score of 100%, but received a code "Not graded - 9" for Gene: CTX-M samples UTI-06, 09 and 10. 2. The laboratory received a score of 100%, but received a code "Not graded - 9" for Gene: dfrA samples UTI-06, and 10. 3. The laboratory received a score of 100%, but received a code "Not graded - 9" for Gene: IMP samples UTI-06, and 09. 4. The laboratory received a score of 100%, but received a code "Not graded - 9" for Gene: mecC samples UTI-06, 07 and 08. 5. The laboratory received a score of 100%, but received a code "Not graded - 9" for Gene: OXA samples UTI-06, and 09. 6. The laboratory received a score of 100%, but received a code "Not graded - 9" for Gene: qnr samples UTI-06, 07 and 08. 7. The laboratory received a score of 100%, but received a code "Not graded - 9" for Gene: sul samples UTI-06, 07 and 08. 8. The laboratory received a score of 100%, but received a code "Not graded - 9" for Gene: vanA/B samples UTI-06, 07, 08 and 10. 9. The laboratory received a score of 100%, but received a code "Not graded - 9" for Gene: VIM samples UTI-06, and 09. 10. The laboratory reported "statistics unavailable for this peer group" for the above mentioned samples. 11. The GS confirmed on 8/26/26 at 10:20 am, the accuracy of the PT results were not verified.

D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), General Supervisor (GS) records and interview with the Technical Consultant (TC), the laboratory failed to verify the accuracy and reliability of Bacteriology testing performed on the Quant Studio 12K Flex in the calendar year 2025. The finding includes: 1. Surveyor review of PT records revealed all following analytes were not verified for accuracy twice annually on the Quant Studio 12K Flex. a) Gene: CTX-M b) Gene: dfrA c) Gene: IMP d) Gene: mecA e) Gene: OXA f) Gene: qnr g) Gene: sul h) Gene: VanA/B i) Gene: VIM 2. Cross refer D5215 3. The GS confirmed 8/26/26 at 1:00 pm, the laboratory did not verify the accuracy for Bacteriology testing performed on the Quant Studio 12K.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on surveyor Procedure Manual (PM) and interview with the General Supervisor (GS), the laboratory failed to follow the procedure "Reagents" from 5/14/21 to 8/26/26. The findings include: 1. The PM stated "3. New Reagent Lot/Shipment Confirmation of Acceptability " "a) New reagent lots and/or shipments are checked against previous reagent lots or with suitable reference material before or concurrently with being placed in service" " b) The director or designee will review the results of the new lot and compare it to the old lot." " c) Documentation of the comparison and slides are filed in the laboratory". 3. There was no documented evidence that above mentioned procedures were performed. 4. The GS confirmed on 8/26/26 at 11:15 am the laboratory did not follow the above mentioned procedures.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specification (PS) records and interview with the General Supervisor (GS), the Laboratory Director (LD) failed to ensure that PS were adequate to perform Bacteriology tests performed on the Applied

bioscience Quantstudio 12K Flex analyzer from 5/14/21 to 8/26/26. The findings include: 1. There was no documented evidence of a stability study. 2. The GS confirmed on 8/26/26 at 12pm the LD failed to ensure that PS were adequate.