

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0666021	(X3) Date Survey Completed 01/29/2020
Name of Provider or Supplier Urological Associates, Pc	Street Address, City, State 3319 Spring Street, Davenport, IA	
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
D2094	<p>ROUTINE CHEMISTRY CFR(s): 493.841(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by laboratory personnel, identifier #5 (refer to the Laboratory Personnel Report) at approximately 1:30 pm on 1/29/2020, the laboratory failed to take and document corrective action when the laboratory received unacceptable PT scores for two out of six PT events (2018 events 1 and 2). The findings include: 1. For 2018 testing event 1, the laboratory received an unacceptable score of 80% for the analyte, alanine aminotransferase. 2. For 2018 testing event 2, the laboratory received an unacceptable score of 80% for the analyte, bicarbonate. 3. At the time of the survey, the laboratory did not document corrective action for the above unacceptable PT scores.</p>
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</p>

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:
Based on review of laboratory policies and procedures and confirmed by laboratory personnel, identifier #5 (refer to the Laboratory Personnel Report) at approximately 2:00 pm on 1/29/2020, the laboratory failed to have the following procedures: staining of slides for non-gynecologic specimens, process for cover slipping non-gynecologic slides, performing testosterone testing on the Tosho chemistry analyzer.

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:
Based on review of the Advantus urinalysis analyzer operator's manual and confirmed by laboratory personnel, identifier #5 (refer to the Laboratory Personnel Report) at approximately 2:30 pm on 1/29/2020, the laboratory director failed to approve, sign, and date the procedure for performing macroscopic (dipstick) urinalysis. The findings include: 1. The laboratory used the Advantus urinalysis analyzer operator's manual as the macroscopic (dipstick) urinalysis procedure. 2. At the time of the survey, the laboratory director did not approve, sign, and date the operator's manual.