

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0666021	(X3) Date Survey Completed 08/19/2021
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 #1 (refer to the Laboratory Personnel Report) at approximately 11:15 am on 8/19/2021, the laboratory failed to document correction action when the laboratory received unacceptable PT scores for one out of five PT events (2020 - event 1) from 1/1/2020 - 8/19/2021. The findings include: 1. For 2020 PT event 1, the laboratory received unacceptable scores of 80% for albumin, 80% for calcium, and 40% for sodium. 2. At the time of the survey, the laboratory did not have documented corrective action for the unacceptable PT scores.</p>
D3037	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11:</p>

15 am on 8/19/2021, the laboratory failed to retain proficiency testing records for a minimum of two years for five out of five PT events from 1/1/2020 - 8/9/2021. The findings include: 1. For 2020 PT event 1, the laboratory did not retain the graded PT scores for chemistry and hematology. 2. For 2020 PT event 2, the laboratory did not retain the graded PT scores for chemistry. 3. For 2020 PT event 3, the laboratory did not retain the graded PT scores for chemistry and hematology and the hematology attestation statement. 4. For 2021 PT event 1, the laboratory did not retain the graded PT scores for chemistry and hematology. 5. For 2021 PT event 2, the laboratory did not retain the graded PT scores for chemistry. 6. At the time of the survey, the laboratory did not retain the above PT records.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on review of personnel records and confirmed by laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at approximately 11:45 am on 08/19/2021 the technical consultant failed to assess and document the competency of individuals performing moderate complexity testing annually for three out of seven testing personnel (laboratory personnel identifiers #2, #4, and #5) in 2020.

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 proficiency testing records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11:15 am on 8/19/2021, the laboratory director failed to ensure that proficiency testing reports are reviewed by the appropriate staff to evaluate the laboratory's performance for five out of five testing events from 1/1/2020 - 8/9/2021. The findings include: 1. The laboratory did not document the review of PT scores. At the time of the survey, the laboratory did not have available the PT scores for review. Refer to D3037. 2. The laboratory did not document corrective action for unacceptable scores. Refer to D2094.