

<p>Statement of Deficiencies</p>	<p>(X1) Provider/Supplier/CLIA Identification Number 44D0234042</p>	<p>(X3) Date Survey Completed 08/19/2020</p>
<p>Name of Provider or Supplier Tennessee Urology Associates Pllc</p>	<p>Street Address, City, State 800 Oak Ridge Turnpike, Suite A-101, Oak Ridge, TN</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p>(X4) ID Prefix Tag</p>	<p>Summary Statement of Deficiencies</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: ===== Based on a complaint survey investigation, the lab director failed to fulfill his duty to provide overall management and direction for moderately complex laboratory testing in accordance with \$493.1407; for specimen collection/handling errors whenever significant deviations from the laboratory's policies were identified and documented (Refer to D6024). =====</p>
<p>D6024</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,</p> <p>This STANDARD is not met as evidenced by: ===== Based on complaint survey</p>

investigation with review of the laboratory's policy and procedure for moderately complex specimen collection and handling and QA (Quality Assurance) Indicator Reports for April 1, 2019 - August 24, 2020 and interviews with 5 testing/processing personnel, laboratory manager and laboratory director, it was determined 101 specimen collection/handling errors were received from clinical sites with no documentation of remedial actions to improve and monitor error rate based on policy /procedures. The findings include: 1. A review of the laboratory's policy and procedure for specimen collection and handling revealed it had not been followed for remedial action and monitoring of errors sent from clinical sites for moderately complex laboratory testing specimens. (reference attached Laboratory Collection and Specimen Handling Guide). 2. A review of the QA indicator reports for April 1, 2019 - August 24, 2020 revealed 101 specimen collection/handling errors were documented from clinical collection sites without remedial action and monitoring to reduce the rate of errors as follows: a. 3 specimen labeling discrepancies b. 14 hemolyzed specimens c. 84 patient test requisition information errors 3. Upon interviews with 5 testing /processing personnel, laboratory manager and laboratory director at survey conclusion at approximately 3:00pm, 8/19/2020 it was confirmed there were significant deviations from the laboratory's established specimen collection/handling policies from clinical specimen collection sites with no remedial actions taken to improve and monitor the error rate for the 16-month period between 2019 and 2020.

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D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:
===== Based on a complaint survey investigation, the laboratory director failed to fulfill his duty to provide overall management and direction for high complexity laboratory testing in accordance with \$493.1445; for specimen collection/handling errors whenever significant deviations from the laboratory's policies were identified and documented (Refer to D6094).
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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 complaint survey investigation with review of the laboratory's policy and procedure for specimen collection and handling of high complexity testing specimens and QA (Quality Assurance) Indicator Reports for April 1, 2019 - August 24, 2020 and interviews with 5 testing/processing personnel, laboratory manager and laboratory director, it was determined the quality assessment program failed to be maintained as 28 specimen

collection/handling errors were received from clinical sites with no documentation of remedial actions to improve and monitor error rate based on policy/procedures. The findings include: 1. A review of the laboratory's policy and procedure for specimen collection/handling revealed it had not been followed for remedial action and monitoring of errors sent from clinical sites for high complexity laboratory testing specimens. (reference attached Laboratory Collection and Specimen Handling Guide). 2. A review of the QA indicator reports for April 1, 2019 - August 24, 2020 revealed 28 specimen collection/handling errors were documented from clinical collection sites without remedial action and monitoring to reduce the rate of errors as follows: a. 1 specimen with only one patient identifier b. 9 urine specimen containers leaking resulting in illegible patient identification c. 2 patient specimen containers with no patient tissue d. 4 tissue specimens with improper fixative e. 3 specimens with no patient test requisition f. 7 specimen labeling discrepancies g. 2 patient specimens double labeled (2 different patients' names) 3. Upon interviews with 5 testing /processing personnel, laboratory manager and laboratory director at survey conclusion at approximately 3:00pm, 8/19/2020 it was confirmed there were significant deviations from the laboratory's established specimen collection/handling policies from clinical specimen collection sites with no remedial actions taken to improve and monitor the error rate for the 16-month period between 2019 and 2020.

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