

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2009241	(X3) Date Survey Completed 10/29/2025
Name of Provider or Supplier Urology Associates, Pc- Dickson	Street Address, City, State 111 Highway 70 East, Suite 104, Dickson, TN	
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
D6004	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)</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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116) and the Automated Survey Processing Environment (ASPEN) Web 116 database, lack of documentation, review of patient testing records, and staff interview, the laboratory director did not maintain compliance with the notification requirements at 493.51, when the state agency was not notified of a change in specialties for Hematology when the laboratory ceased testing in 2024. The findings include: 1. Review of the Form CMS-116 revealed that Hematology was not listed as a specialty. 2. Review of the ASPEN Web 116 database revealed that Hematology was listed as a specialty. 3. The laboratory failed to provide documentation that the state agency was notified of the change in specialties. 4. A review of test reports revealed that the last post-vasectomy semen analysis was performed on May 8, 2024 (Patient ID 1987630). 5. The technical consultant confirmed the laboratory ceased testing for post-vasectomy semen analysis in May of 2024 and did not notify the state agency of the change during an interview on 10/29/2025 at 9:15 a.m.</p>

D6005**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(c)

(c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities.

This STANDARD is not met as evidenced by:

Based on a lack of documentation and staff interview, the laboratory director failed to perform onsite laboratory visits every 6 months, with at least 4 months between the two onsite visits as required. The findings include: 1. The laboratory director's onsite visits were not performed in 2025. 2. The technical consultant confirmed the findings on 10/29/2025 at 9:30 a.m.