

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2009241	(X3) Date Survey Completed 11/15/2023
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
D5431	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure manual, the centrifuge manufacturer's operators manual, lack of documentation and email communication, the laboratory failed to have documentation of RPMs and timer checks for the Drucker model 642VES centrifuge in 2021, 2022, and 2023. The findings include: 1. Observation of the laboratory on 11/15/23 at 8:45 am revealed a Drucker model 642VES (serial number 560514-51) centrifuge on the counter in use for processing urine samples in preparation for urine sediment examination. 2. Review of the laboratory procedure revealed that urine specimens are to be centrifuged for 1500-2000 RPM for five minutes. 3. Review of the manufacturer's operators manual for the Horizon Drucker 642VES centrifuge revealed the following under the specifications section: Speed Range: 1,000 - 3,800 (+/-100) RPM Timer: Electronic, 1 to 30 minutes, preset to 10 minutes +/- 1% 4. No documents were available on the date of the survey for RPM and timer checks of the centrifuge. 5. Email communication received from the technical consultant on 11/20/2023 at 8:03 am confirmed the laboratory service records for the centrifuge did not contain the measurements of the RPM and timer checks in 2021, 2022 or 2023. Work key: RPM=revolutions per minute</p>