

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D1016681	<b>(X3) Date Survey Completed</b>  11/07/2023
<b>Name of Provider or Supplier</b>  Urology Associates, Pc-Stonecrest	<b>Street Address, City, State</b>  300 Stonecrest Pkwy Ste 490, Smyrna, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5401</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of laboratory procedure, and staff interview, the laboratory failed to follow it's own procedure for processing patient samples for urine sediment examination when the centrifuge in use exceeded the speed and time specifications in the laboratory procedure in 2023. The findings include: 1. Observation of the laboratory on 11/07/2023 at 10:25 am revealed a Horizon Druker Diagnostics 642E centrifuge (serial 230413JA143) in use to process patient samples for urine sediment examination. The factory calibration sticker from 04/28/2023 indicated a speed of 3593 revolutions per minute (RPM) and a time of 15 minutes. 2. Review of the laboratory procedure titled " SIEMENS CLINITEK STATUS PLUS URINE DIPSTICK AND URINE SEDIMENT EXAMINATION" section "MICROSCOPIC EXAMINATION OF URINE SEDIMENT PROCEDURE" step two, revealed urine samples were to be centrifuged for five minutes at 400-450 G (1500-2000 rpm). 3. Interview on 11/07/2023 at 12:30 pm with the office manager and technical consultant confirmed the Horizon Druker Diagnostics 642E centrifuge used to process patient samples for urine sediment examination did not have speed and time settings that were consistent with the laboratory's procedure.</p>