

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2243450	(X3) Date Survey Completed 10/15/2024
Name of Provider or Supplier Urology Associates, Pc - St Thomas West	Street Address, City, State 4230 Harding Pike, Suite 301, Nashville, 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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory observation, review of the laboratory procedure manual, patient test records, the laboratory maintenance log, and staff interview, the laboratory failed to perform daily temperature checks and laboratory cleaning for one of five testing dates reviewed in 2023 and 2024. The findings include: 1. Observation of the laboratory on 10/15/2024 at 8:50 a.m. revealed a Siemens Clinitek Status Plus (Serial Number 331315) in use for patient urinalysis testing and a Henry Schein microscope (ID: G38L 20210641) in use for patient urine microscopic testing. 2. A review of the laboratory procedure "DAILY/WEEKLY TASKS" revealed requirements for daily temperature monitoring, countertop cleaning, microscope cleaning, and centrifuge cleaning. 3. A random review of patient test records revealed the laboratory performed patient urinalysis with microscopic testing on the following dates: -09/09/2024 (Patient: 1478980) -06/20/2024 (Patient: 2168510) -02/14/2024 (Patient: 1745110) -10/19/2023 (Patient: 1994900) -05/03/2023 (Patient: 1723400) 4. A review of the laboratory maintenance log revealed documentation of "-----NO CLINIC-----" on 09/09/2024. 5. An interview with the technical consultant on 10/15/24 at 11:30 a.m. confirmed the findings.</p>
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--</p>

At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of the laboratory procedure manual, patient test records, laboratory quality control (QC) logs, and staff interview, the laboratory failed to perform and document negative and positive urinalysis QC for the Siemens Clinitek Status Plus (Serial Number SN331315) or a review of microscopic reference material for one of five testing dates reviewed in 2023 and 2024. The findings include: 1. Observation of the laboratory on 10/15/24 at 8:50 a.m. revealed the Siemens Clinitek Status Plus (Serial Number SN331315) in use for patient urinalysis testing and a Henry Schein microscope (ID: G38L 20210641) in use for patient urine microscopic testing. 2. A review of the laboratory procedures "SIEMENS CLINITEK STATUS PLUS URINE DIPSTICK AND URINE SEDIMENT EXAMINATION" and "DAILY/WEEKLY TASKS" revealed requirements to run two levels of QC (normal and abnormal) daily, before running patient samples. 3. A random review of patient test records revealed the laboratory performed patient urinalysis with microscopic testing on the following dates: -09/09/2024 (Patient: 1478980) -06/20/2024 (Patient: 2168510) -02/14/2024 (Patient: 1745110) -10/19/2023 (Patient: 1994900) -05/03/2023 (Patient: 1723400) 4. A review of the laboratory QC log revealed documentation of "9-9 - 9-10 NO CLINIC" with no printouts of Clinitek Status Plus urinalysis QC or a review of microscopic reference material documented for 09/09/2024. 5. An interview with the technical consultant on 10/15/24 at 11:30 a.m. confirmed the findings.