

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D2052838	<b>(X3) Date Survey Completed</b>  02/22/2023
<b>Name of Provider or Supplier</b>  Urology Associates/Minnesota Urology	<b>Street Address, City, State</b>  6525 France Ave So #208, Edina, MN	
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>D5473</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by:                      . Based on document review and interview with laboratory personnel, the laboratory failed to document Histopathology quality control (QC) procedures performed to test Hematoxylin and Eosin (H&amp;E) stain for intended reactivity each day of use in 2022. The laboratory performed approximately 9,311 Histopathology tests on patient samples annually. Findings are as follows: 1. The laboratory performed Histopathology testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory on February 22, 2023 at 10:05 a.m. 2. The QC Evaluation of Pathology Slides procedure and the H&amp;E Staining procedure found in the Histology SOP (Standard Operating Procedure) white binder included procedures for reviewing the stain quality of the H&amp;E slides daily for acceptability and documenting it on the appropriate log by the Pathologist. 3. A patient's prostate biopsy (ID # xxx550), performed on 06/08/2022, documents were reviewed on the day of survey. It was found that the patient had 18 slides evaluated on 06/08/2022, each stained with H&amp;E. Review of the H&amp;E QC log, found that the daily QC evaluation and documentation was not performed on the day of patient testing. The documentation of the assessment of the staining characteristics were documented weekly, when the reagents were changed, not each day of use. 4. In an interview on 12:05 p.m. on February 22, 2023, the LD confirmed the above findings. *H&amp;E = Hematoxylin and Eosin</p>