Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D2052838	06/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
Urology Associates/Minnesota Urology	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the testing personnel (Pathologist) failed to document the acceptability of the Immunohistochemical Stain Quality Control (QC) slides on each day of patient specimen testing. Findings are as follows: 1. The laboratory performed Pathology testing under the subspecialty of Histopathology as confirmed by the Histology Technologist (HT) during a tour of the laboratory on 06/25/18 at 9:35 a.m. 2. A BioCare Medical Intellipath Automated Slide Staining System was observed as present and available for use during the tour of the laboratory. 3. A requirement for the review of accuracy and quality of Immunohistochemical Stain QC slides by the Pathologist was established in the PIN-4 Cocktail (CK5 + CK14 + p63 + p504S) Immunohistochemical Stain procedure located in the Procedure manual. 4. In an interview on 6/25/18 at 10:15 a.m., HT stated that surgical prostrate tissue was sourced from a local hospital for use for positive staining QC slides. 5. Documentation of inclusion of Immunohistochemical Stain QC slide processing was not found during review of the following laboratory record (Immuno Daily Run Log): Date Range: 01/03/18 to 6/22/18 # of Staining Batches Performed: 99 # of Patient Cases Evaluated: 345 # of Patient Slides Stained: 696 6. Documentation of processing

	of Immunohistochemical Stain QC slides was not found during review of the BioCare Medical Intellipath IHC Batch Reports obtained for the same time period and testing dates. 7. In an interview on 07/2/18 at 9:35 a.m.., the HT confirmed the above finding.