

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D1107456	(X3) Date Survey Completed 12/19/2019
Name of Provider or Supplier Urology Associates Of Grand Rapids, P C	Street Address, City, State 245 Cherry Street Se Suite 202, Grand Rapids, MI	
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	<p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: . Based on procedure review, record review, and interview with the General Supervisor (GS), the laboratory failed to document the onsite professional interpretation of the Hematoxylin & Eosin (H&E) differential stain quality for 12 (NAJ17-2767, NAJ18-954, NAJ18-1479, NAJ18-2019, NAJ19-136, NAJ19-736, NAJ19-1190, NAJ19-1466, SAJ17-4918, SAJ18-765, SAJ18-0009, and SAJ18-2965) of 21 patient reports audited from December 2017 to December 2019. Findings include: 1. Review of the "Daily Assessment of Stain and Prep Quality" procedure states, "The pathologist will dictate a description of the quality of the stain and prep into the microscopic section of each report." 2. Record review revealed for 12 of 21 patient reports audited, the on-site Hematoxylin & Eosin (H&E) stain interpretation for the professional component of the slide review was not documented on the final patient report for the following patient reports audited: a. NAJ17-2767 b. NAJ18-954 c. NAJ18-1479 d. NAJ18-2019 e. NAJ19-136 f. NAJ19-736 g. NAJ19-1190 h. NAJ19-1466 i. SAJ17-4918 j. SAJ18-765 k. SAJ18-0009 l. SAJ18-2965 3. During the interview on 12/19/19 at 11:00 am, the GS confirmed the on-site H&E stain interpretation was not performed and documented on the final patient reports.</p>