

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D0431110	<b>(X3) Date Survey Completed</b>  04/17/2025
<b>Name of Provider or Supplier</b>  Illinois Urologic Health Surgeons	<b>Street Address, City, State</b>  2937 State Route 178, Utica, IL	
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>D5601</b>	<p><b>HISTOPATHOLOGY</b> 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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with the laboratory director (LD); the laboratory failed to document dermatopathology immunohistochemical (IHC) stain positive and negative reactivity for four of four patient test reports reviewed from 2023 through the date of survey, 04/17/2025. Findings include: 1. Review of laboratory policies and procedure revealed the policy, "Complete Overview", which stated, under "SUBJECT: Quality Control Stains", "Immunohistochemical stains will all be interpreted with the use of positive control stains and a negative control tissue stain." 2. Review of patient testing logs for IHC staining found no documentation of negative reactivity, only positive reactivity was documented for four of four patient test reports reviewed with IHC stains p63, CK34betaE12, and racemase from 2023 through the date of survey, 04/17/2025. Report Date: Case #: IHC QC documentation: 11/10/2023 PLS23-05510 Positive only 12/14/2023 PLS23-06200 Positive only 01/31/2024 PLS24-00374 Positive only 04/30/2024 PLS24-02528 Positive only 3. Interview with the LD on 04/17/2025, at 2:45 pm, confirmed the laboratory failed to document dermatopathology IHC stain positive and negative reactivity for four of four patient test reports reviewed from 2023 through the date of survey, 04/17/2025.</p>