

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2118978	(X3) Date Survey Completed 12/15/2022
Name of Provider or Supplier Wyoming Valley Pathology Assoc	Street Address, City, State 300 Laird Street Sutie A2, Wilkes Barre, PA	
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 review of quality control (QC) records and interview with testing personnel #5 (TP), the laboratory failed to document positive and negative reactivity every day of patient testing for the immunohistochemical (IHC) stains from 11/17/2020 to 12/15/2022. Findings include: 1. On the day of survey 12/15/2022 at 10:30 a.m., review of stain QC records revealed, that a positive and negative control were not documented for the following immunohistochemical (IHC) stain from 11/17/2020 to 12/15/2022: - CD 3 - CD 5 - CD 10 - CD 20 - CD 23 - CD 34 - CD 138 - BCL-2 - BCL-6 - Cyclin D1 - Kappa - Lambda - Ki 67 - PAN CK - CK34B12 - P63 - CK7 - CK20 - PS04S - P53 - H. Pillory - LCA CD45 2. TP #5 confirmed the findings above on 12/15/2022 around 10:30 am.</p>