

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2172326	(X3) Date Survey Completed 10/06/2020
Name of Provider or Supplier Paterson Diagnostics, Inc	Street Address, City, State 11912 Kanis Road, Suite F4, Little Rock, AR	
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: Through a review of 2020 Special Request/Daily Tissue Quality QC forms and an interview with laboratory staff, it was determined the laboratory failed to document reactivity of immunohistochemical (IHC) stains and failed to document all control procedures performed when IHC stains fail to react as expected. Survey findings include: A. During a review of randomly selected Special Request/Daily Tissue Quality QC forms from March, May, and August of 2020 it was determined that two out of fifty Special Request/Daily Tissue Quality QC forms reviewed were incomplete. B. The Special Request/Daily Tissue Quality QC form dated 5/13/2020 (case #C20-316) includes a comment in the sections titled Pathologist QC Review that states, "CMV positive control not working". The form includes a space to record corrective actions taken. There was no documentation of corrective actions for the failed CMV positive control. C. The Special Request/Daily Tissue Quality QC form dated 8/27/2020 (case #G20-925) has documentation that IHC stain (MLH1/MSH2/PMS2/MSH6) was performed. The section of the form titled "Pathologist QC Review" has no documentation of the acceptability of the stain or the controls. D. In an interview at 12:35 on 10/6/2020 employee #4 (as listed on the form CMS-209) confirmed the lack of documented corrective actions and lack of documented quality control acceptability on the two Special Request/Daily Tissue Quality QC forms.</p>