

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  03D1037969	<b>(X3) Date Survey Completed</b>  05/17/2019
<b>Name of Provider or Supplier</b>  Clin-Path Associates, Plc	<b>Street Address, City, State</b>  1955 W Frye Rd, Pathology Laboratory, Chandler, AZ	
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>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 an immunohistochemical (IHC) control report for accession ID: S19-000948 and interview with the facility personnel, the laboratory failed to indicate lot numbers and expiration dates for the IHC controls used in staining patient slides on the stain acceptability sign off documentation provided. Findings include: 1. There was no indication on the specific IHC controls utilized in patient testing including lot numbers and expiration dates. 2. The facility personnel could not identify where the IHC stain control lot numbers and expiration dates were being recorded.</p>