

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0508312	<b>(X3) Date Survey Completed</b> 12/28/2021
<b>Name of Provider or Supplier</b> Clinical Pathology Associates	<b>Street Address, City, State</b> 1150 N 18th Suite 102, Abilene, TX	
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>D0000</b>	The laboratory was surveyed and found to be in compliance with the conditions of participation found in the CLIA regulations at 42 CFR 493 and recertification is recommended.
<b>D5475</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(e)(3)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of patient records, quality control records, and interview with facility personnel, the laboratory failed to document negative reactivity each time of use for the Cytokeratin (CK 5/6) immunohistochemical stain for two of two patient records reviewed for the month of November 2021. The findings included: 1. Two patient records where the Cytokeratin (CK5/6) immunohistochemical stain was used in patient testing were identified for the month of November 2021: OS2105203 - received 11/16/2021 OS2105345 - received 11/23/2021 2. Based on review of quality control records, positive control reactivity was graded, but negative control reactivity was not documented for the dates of processing OS2105203 and OS2105345. 3. In an interview at 16:11 hours on 12/28/2021, the Laboratory Manager confirmed there was no documentation of negative reactivity on immunohistochemical stains such as the CK5/6 immunohistochemical stain. Instead there was a comment on the patient report that stated the following: "Any immunohistochemical stains or special stains performed had quality controls that were within an acceptable range, unless otherwise noted."</p>