

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2021404	<b>(X3) Date Survey Completed</b>  03/26/2025
<b>Name of Provider or Supplier</b>  Clinical Pathology Associates	<b>Street Address, City, State</b>  1201 W 38th St, Austin, 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 the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended. Standard level deficiency was cited.
<b>D5473</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(e)(2)(g)</p> <p>(e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, test reports, quality control (QC) records, pre-survey paperwork, and interview, the laboratory failed to document the reactivity of the Papanicolaou stain to ensure predictable staining characteristics for their quality control used in diagnostic interpretations of nongynecological cytology specimens for 2 out of 5 days of testing reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled "Microscopic Examination of Anatomic Pathology Specimens." revised 03/15/2025, under Testing Accuracy and Quality Assurance stated, "The pathologist will review the staining and slide quality each day as well as the quality of the gross for surgical cases. The results of this review are recorded on the CPA Daily Log of Outpatient Surgical Pathology and Cytology Slide Quality. A rating of 'Good Quality' indicates the following: 2. Cytology Papanicolaou stained slides: a. Slide Quality: Processing Acceptable (sufficient cellularity for diagnosis) Papanicolaou stain: i. Nuclei (Chromatin) blue ii. Keratin orange iii. Cytoplasm shades of blue-green iv. Squamous cells, RBCs, nucleoli, and cilia shades of pink iii. Cover slipped appropriately." B. Random review of patient test reports against the Surgical and Cytology Stain Quality Log revealed two out of five days of testing without QC for the Papanicolaou stain as listed by date reported and accession numbers: Date Reported Accession Number 1. 06</p>

/28/2024 ATNG24-000065 2. 02/19/2024 AT24-001311 C. Review of the CMS Form 116 showed an estimated annual test volume of 169 in nongynecological cytology. D. Interview with the Client Services Manager on March 26, 2025 at 1315 hours in the conference room confirmed there was no documentation of the QC on those days of testing.