

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2129189	<b>(X3) Date Survey Completed</b>  10/17/2024
<b>Name of Provider or Supplier</b>  Clinical Pathology Associates Name	<b>Street Address, City, State</b>  Pathology Dept 1st Floor, 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 deficiencies were cited.
<b>D5473</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (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. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, quality control (QC) records, test reports, presurvey paperwork, and interview, the laboratory failed to document the intended reactivity to ensure predictable staining characteristics for the Papanicolaou (PAP) stain used in cytology interpretations of non-GYN cases stained predictably for two of four cases reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled Microscopic Examination of Anatomic Pathology Specimens, revised 04/30/2020, 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. The results of this review are recorded on the CPA Daily histology and Cytology QA Log. A rating of "Good Quality" indicates the following respectively: 1 Histopathology H&amp;E stained slides a H&amp;E stain: i. Nuclei and basophilic structures stain blue ii. Cytoplasm acidophilic structures stain pink b. Gross quality is acceptable i. Specimen was submitted with correct measurements ii. Specimen number of pieces is acceptable iii. No cross contamination of specimens c. Slide quality is acceptable i. Slide demonstrates tissue as expected ii. No cutting artifact that impacts rendering of a diagnosis as defined by the pathologist. iii. Cover</p>

slipped appropriately 2. Cytology Papanicolaou stained slides: a. Slide Quality: i. Processing Acceptable (sufficient cellularity for diagnosis) ii. Papanicolaou stain: 1. nuclei (Chromatin) blue 2. Keratin orange 3 Cytoplasm shades of blue-green 4. Squamous cells, RBCs, nucleoli, and cilia shades of pink iii. Cover slipped appropriately 3. Special Stains/immunohistochemistry stains are assessed only when performed. a. When a special stain is performed, there will be a working control that is performed with that stain. b. The pathologist will assess the patient and control stain for quality and results. i. Stain performance is based on the results criteria outlined in the attached documents from CPA. These are maintained on location for reference for testing personnel. c. The assessment of this stain is documented in the pathology report. Language similar to the following will be used: "XX stain is performed in the presence of a(n) appropriately functioning/positive control." This statement should be interpreted as the assessment that the stain functioned as expected and is adequate for diagnosis." B. Random review of patient test reports against the Surgical and Cytology Stain Quality Log revealed two out of four days of testing without QC for the PAP stain as listed by date reported and accession numbers: Date Reported Accession Number 1. 12/22/2023 PAP23-012245 2. 01/30/2024 AT24-000790 C. Review of the CMS Form 116 showed an estimated annual test volume of 6349 in histopathology. D. Interview with the Client Services Manager on November 17, 2024 at 1505 hours in the office confirmed there was no documentation of the QC on those days of testing after a review of the records.

**D5601**

**HISTOPATHOLOGY**  
CFR(s): 493.1273(a)(f)

(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.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's policies and procedures, quality control (QC) records, test reports, presurvey paperwork, and interview, the laboratory failed to document the intended reactivity to ensure predictable staining characteristics for the Immunohistochemical (IHC) stains and Special stains for the diagnostic interpretation of histopathology specimens for three of three reports reviewed. Finding follow. A. Review of the laboratory's policy and procedure titled Microscopic Examination of Anatomic Pathology Specimens, revised 04/30/2020, 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. The results of this review are recorded on the CPA Daily histology and Cytology QA Log. A rating of "Good Quality" indicates the following respectively: 1 Histopathology H&E stained slides a H&E stain: i. Nuclei and basophilic structures stain blue ii. Cytoplasm acidophilic structures stain pink b. Gross quality is acceptable i. Specimen was submitted with correct measurements ii. Specimen number of pieces is acceptable iii. No cross contamination of specimens c. Slide quality is acceptable i. Slide demonstrates tissue as expected ii. No cutting artifact that impacts rendering of a diagnosis as defined by the pathologist. iii. Cover slipped appropriately 2. Cytology Papanicolaou stained slides: a. Slide Quality: i. Processing Acceptable (sufficient cellularity for diagnosis) ii. Papanicolaou stain: 1. nuclei (Chromatin) blue 2. Keratin orange 3 Cytoplasm

shades of blue-green 4. Squamous cells, RBCs, nucleoli, and cilia shades of pink iii. Cover slipped appropriately 3. Special Stains/immunohistochemistry stains are assessed only when performed. a. When a special stain is performed, there will be a working control that is performed with that stain. b. The pathologist will assess the patient and control stain for quality and results. i. Stain performance is based on the results criteria outlined in the attached documents from CPA. These are maintained on location for reference for testing personnel. c. The assessment of this stain is documented in the pathology report. Language similar to the following will be used: "XX stain is performed in the presence of a(n) appropriately functioning/positive control." This statement should be interpreted as the assessment that the stain functioned as expected and is adequate for diagnosis." The policy did not address the documentation of controls for IHC and Special stains. The laboratory's practice was to document controls for the IHC and Special stains only in the test report. B. Review of the Surgical and Cytology Stain Quality Log did not have a column to record the QC for Immunohistochemical (IHC) or Special stains. C. Random review of 18 test reports from 07/13/2022 - 08/27/2024 showed 3 with IHC/special stains. Three of three test reports/cases did not include QC for the intended reactivity to ensure predictable staining characteristics for the following IHC and Special stains: Surgical Path # Date Reported IHC/Special Stain 1. D0090916-2201 12/15/2022 PAS 2. DP23-007842 08/23/2023 Sox-10, PRAME 3. DP24-006516 06/18/2024 PAS D. Review of the CMS form 116 showed approximately 6349 histopathology specimens were reported annually. E. Interview with the Client Services Manager on October 17, 2024 at 1430 hours confirmed the performance of the QC for the IHC and Special stains was not recorded on a QC log.