Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2129188	10/17/2024
Name of Provider or Supplier	**Street Address, City, State**	
Clinical Pathology Associates	11111 Research Blvd Snw, Austin, TX	

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
D0000	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.
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 one of one 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 iiii. 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 04/29/2022 - 09/04/2024 showed 1 with IHC/special stains. One of one test reports/cases from 03/03/2023 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. AT23-001040 03/03/2023 CD3, CD20, CD10, CD21, BCL-2, BCL-6, Ki-67 D. Review of the CMS form 116 showed approximately 2890 histopathology specimens were reported annually. E. Interview with the Client Services Manager on October 17, 2024 at 1720 hours confirmed the performance of the QC for the IHC and Special stains was not recorded on a QC log.