Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2129190	11/06/2024
Name of Provider or Supplier	**Street Address, City, State**	
Clinical Pathology Associates	Pathology Dept 1st Floor, Round Rock, 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.
D3043	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7) The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's policies and procedures, slide review, and interview, the laboratory failed to retain slides from its diagnostic interpretation of histopathology specimens for at least 10 years for two out of 20 cases reviewed from 2019 - 2024. Findings follow. A. Review of the laboratory's policies and procedures did not address slide retention. B. Review of slides showed slides from the following case numbers were unavailable for review: 1. 03/13/2023 AT23-001396 missing slide 1 2. 12/12/2023 AT23-010647 missing slide B5 C. Review of the CMS form 116 showed approximately 507 histopathology specimens were reported annually. D. Interview with the Client Services Manager on November 6, 2024 at 1400 hours in the laboratory confirmed the slides were missing. II. Based on review of the laboratory's policies and procedures, cassette review, and interview, the laboratory failed to retain cassettes from its diagnostic interpretation of histopathology specimens for at least 2 years for one out of 18 cases reviewed from 2022 - 2024. Findings follow. A. Review of the laboratory's policies and procedures did not address cassette retention. B. Review of cassettes showed cassette B5 from case number AT23-010647 on 12/12

	/2023 was missing unavailable for review. C. Review of the CMS form 116 showed approximately 507 histopathology specimens were reported annually. D. Interview with the Client Services Manager on November 6, 2024 at 1430 hours in the laboratory confirmed the cassette was missing.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (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. 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 Hematoxylin and Eosin (H&E) stain to ensure predictable staining characteristics for their quality control used in diagnostic interpretations of histopathology specimens for five out of 18 days of testing 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. Histology H&E stained slides a. H& E stain: i. Nuclei and basophilic structures stain blue ii. Cytoplasm and 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." B. Random review of patient test reports against the Surgical and Cytology Stain Quality Log - Monthly Summary Report revealed five out of 18 days of testing without QC for the H&E stain as listed by date reported and accession numbers: Date Reported Accession Number 1. 01/10/2023 GY0001369-2301 2. 02/01/2023 GY0006496-2301 3. 03/13 /2023 AT23-001396 4. 08/22/2023 DP23-007878 5. 08/22/2023 DP23-007895 C. Review of the CMS Form 116 showed an estimated annual test volume of 507 in histopathology. D. Interview with the Client Services Manager on November 6, 2024 at 1420 hours in the laboratory confirmed there was no documentation of QC on those days of testing after a review of the records.