Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2052455	07/17/2024
Name of Provider or Supplier	**Street Address, City, State**	
Clinical Pathology Associates	1500 Red River Pathology Dept Lower Level, 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.
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 six out of 14 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 revealed six out of 14 days of testing without QC for the H&E stain as listed by date reported and accession numbers: Date Reported Accession Number 1. 09/21/2023 AT23-007841 2. 10/16/2023 AT23-008716 3. 12/20/2023 AT23-010948 4. 02/08 /2024 DP24-001284 & DP24-001327 5. 04/25/2024 AT24-003669 6. 04/26/2024 DP24-004641 C. Review of the CMS Form 116 showed an estimated annual test volume of 7836 in histopathology. D. Interview with the Client Services Manager on July 17, 2024 at 1740 hours in the office confirmed there was no documentation of the QC on those days of testing after a review of the records.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. 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 director failed to ensure the quality control programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Findings follow. 1. 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 six out of 14 days of testing reviewed (see D5473).