

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2129190	(X3) Date Survey Completed 07/08/2026
Name of Provider or Supplier Clinical Pathology Associates	Street Address, City, State 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 Oculus Pathology St David's Surgical laboratory was found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, CLIA requirements for laboratories as a result of a recertification survey on 07/08/2026 and recertification is recommended. Standard level deficiency was cited.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (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. 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 four out of nine days of testing reviewed from Jan 2025 - May 2026. Findings follow. A. Review of the laboratory's policy and procedure titled "Microscopic Examination of Anatomic Pathology Specimens." reviewed 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 OP Daily Log of Outpatient Surgical Pathology and Cytology Slide Quality. A rating of 'Good Quality' indicates the following: 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 nine patient test reports against the Surgical and Cytology Stain Quality Summary for CPA St David's Surgical Hospital log revealed four out of nine days of testing without QC for the H&E stain as listed by Accession number and date received and date reported: Accession # Date Rec'd Date Reported 1. AT25-001275 02/03/2025 02/04/2025 2. AT25-008711 07/01/2025 07/02/2025 3. AT25-011501 09/02/2025 09/09/2025 4. AT26-050060 01/16/2026 01/21/2026 C. Review of the CMS Form 116 showed an estimated annual test volume of 785 in histopathology. D. Interview with the Clinical Laboratory Service Manager on July 8, 2026 at 1030 hours in the laboratory confirmed the findings.