Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1000595	02/05/2025
Name of Provider or Supplier	**Street Address, City, State**	
Pathology Arts Inc	549 Queensland Circle, Ste 101, Corona, CA	

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
D3013	FACILITIES CFR(s): 493.1101(e) Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation. This STANDARD is not met as evidenced by: Based on the surveyor's observation during the laboratory tour on the day of the survey February 5, 2025, and interviews with laboratory director (LD) and testing personnel (TP), it was determined that the laboratory failed to maintain and store patients' histopathology sample slides under conditions that ensure security and proper preservation. Findings included: 1. On February 5, 2025, at approximately 3:30 p.m., the surveyor observed during the laboratory tour that multiple boxes of histopathology patients' sample slides were stored directly on the floor on the walkway entrance to the laboratory. 2. The LD and TP confirmed that histopathology patients' sample slides were maintained and stored under conditions which do not ensure security and proper preservation. 3. Based on the laboratory testing declaration signed and dated by the laboratory director the laboratory processes and stores approximately 5,000 histopathology samples annually.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

	This STANDARD is not met as evidenced by: Based on the surveyors' observation during the laboratory's tour reagent materials used in the laboratory and interviews with the laboratory director (LD) and testing personnel (TP); it was determined that the laboratory failed to label various reagents used in the laboratory to indicate the reagent's name, opening, preparation, and expiration dates when such reagents are used in the laboratory. The findings included: 1. Based on the surveyor's observation during the laboratory tour on February 5, 2025, at approximately 4:00 pm.; no received, opening, preparation, or expiration date labels were used or documented for various reagents (vinegar, dyes, alcohols, etc.) used throughout the laboratory. 2. The laboratory's LD and TP affirmed in an interview conducted on 2/5/2025, at approximately 4:15 p.m. that the reagents mentioned in 1. above were not labeled with the received date, opening, preparation, and expiration dates or documented in a reagent preparation log. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed approximately 5,000 clinical tests for which various reagents were not labelled.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policies and procedure, five (5) randomly selected patient records, and interviews with laboratory director (LD) and testing personnel (TP); it was determined that the laboratory failed to perform and document preventive maintenance (PM) and calibration as defined by the manufacturer and with at least the frequency specified by the manufacturer for microscopes and small equipment used in the laboratory for sample testing. The findings included: 1. At the time of survey on 2/5/2025, based on the surveyors' observation during the laboratory tour and review of records documentation at approximately 1:30 p.m3:15 p.m., it was determined that the laboratory failed to perform PM and calibration on the microscopes, cytospins, and small equipment used in the laboratory for sample processing: thermometers, vortexes, rotators, and timers for the years 2023 and 2024. 2. The LD and TP affirmed on February 5, 2025, at approximately 4:00 p.m. that maintenance and calibration was missed for the equipment mentioned in #1 for the years 2023 and 2024. 3. According to the laboratory's testing declaration submitted by the LD, the laboratory performed approximately 5,000 histopathology samples annually for which no preventive maintenance of microscopes, cytospins, small equipment used for sample processing was performed.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) (e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by:

	Based on the surveyor's review of the laboratory's policies and procedures, five (5) randomly selected patients test records, observation during the laboratory tour, and interviews with the laboratory director and testing personnel on February 5, 2025; it was determined that the laboratory director is cited herein due to failure to ensure that several aspects of the preanalytic, analytical, and postanalytic phases of the laboratory testing were monitored. See D3013, D5415, and D5429.