Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2147408	03/24/2021
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Pathology	4208 Sw Lee Blvd, Lawton, OK	

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 recertification survey was performed on 03/24/2021. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director, histotechnician, and laboratory assitant at the conclusion of the survey.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of manufacturer's instructions, observation, and interview with the histotechnician, the laboratory failed to ensure the Sakura Tissue-TEK SCA and coverslipped slides had been stored as required by the manufacturer. Findings include: (1) On 03/24/2021 at 10:00 am, the histotechnician stated the following to the surveyors: (a) The laboratory performed processing, staining, and microscopic examination of histopathology and non-gynecologic specimens; (b) The Sakura Tissue-Tek SCA coverslipper was an automated instrument used to coverslip the specimens that were mounted on microscope slides, using a resin coated film instead of cover glass and liquid mounting media. (2) On 03/24/2021 at 11:20 am, surveyor #1 observed the following and the histotechnician stated: (a) The Sakura Tissue-Tek was housed in a separate room denoted as room 2; (b) The coverslipped slides (after slide interpretation) were stored in the hall area outside of the processing room. (3) Surveyor #1 reviewed the manufacturer's environmental instructions contained in the

	"Operating Manual" for the Sakura Tissue-Tek coverslipper with the following identified: (a) Under the heading "Environmental Factors" on page 2.1, the manufacturer required the analyzer be stored at a relative humidity of 30-70%; (b) Under the heading "Storage of Coverslipped Slides" on page 3.3, the manufacturer required the coverslipped slides be stored at a relative humidity of less than 50% and a temperature of 19-25 degrees Celsius (67-77 degrees Fahrenheit). (4) Surveyor #1 reviewed the manufacturer's storage requirements with the histotechnician, who stated to surveyor #1 on 03/24/2021 at 12:30 pm, the laboratory did not monitor the humidity of the room where the Sakura Tissue-Tek was stored and did not monitor the temperature and humidity in the area where the coverslipped slides were stored. 39088 Based on a review of manufacturer's instructions, observation, and interview with the histotechnician, the laboratory failed to ensure the Cell Solutions F50 had been stored as required by the manufacturer. Findings include: (1) On 03/24/2021 at 10:00 am, the histotechnician stated the following to the surveyors: (a) The laboratory performed processing, staining, and microscopic examination of histopathology and non-gynecologic specimens. (2) On 03/24/2021 at 10:15 am, surveyor # 2 observed the following and the histotechnician stated: (a) The Cell Solutions F50, used in specimen slide preparation, was housed in room 1. (3) Surveyor #2 reviewed the manufacturer's environmental instructions contained in the "Operating Manual" with the following identified: (a) Cell Solutions F50 - Under the heading "Equipment Specifications " on page 2-1, the manufacturer required the Cell Solutions F50 be stored at a relative humidity of 30-80%. (4) Surveyor #2 reviewed the manufacturer's storage requirements with the histotechnician, who stated to surveyor #2 on 03/24 /2021 at 12:45 pm, the laboratory did not monitor the humidity of the room where the equipment was stored.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document 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 a review of records, manufacturer's instructions, and interview with the histotechnician, the laboratory failed to perform maintenance procedures as required by the manufacturer for 52 of 52 weeks. Findings include: (1) On 03/24/2021 at 10:00 am, the histotechnician stated the following to the surveyors: (a) The laboratory performed processing, staining, and microscopic examination of histopathology and non-gynecologic specimens. (2) Surveyor #2 reviewed the Leica ASP 300S Tissue Processor manufacturer's weekly maintenance requirements located in Section 7.3 "Preventative maintenance schedule" of the Operator's Manual, which required the following maintenance: (a) Weekly (i) Lubricate reagent bottle "O" rings and check for damage. (ii) Inspect and, if necessary, clean retort lid seal. (iii) Inspect and, if necessary, clean wax bath lid seal. (iv) Inspect and, if necessary, clean wax bath strainers. (v) Inspect wax bath air vent and, if necessary, clear. (vi) Inspect and empty condensate bottle. Clear inlet holes if necessary. (3) Surveyor #2 then reviewed records from January 2020 through December 2020 with the following identified: (a) There was no documentation to prove the weekly maintenance had been performed. (4) Surveyor #2 reviewed the findings with the histotechnician. The histotechnician stated on 03/24/2021 at 12:55 pm the weekly maintenance had not been documented as indicated above.