Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0656760	06/25/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pc Pathology Laboratory Associates, Inc	1900 N 14th Street, Ponca City, 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 validation survey was performed on 06/25/19. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the chief quality officer, risk manager, pathology assistant, CCU manager, MS director (cardiac rehab/swing bed), BFC director, laboratory director, POC (point of care)/LIS (laboratory information system) coordinator, microbiologist, urinalysis lead, hematology/coagulation lead, quality, director of facilities, CEO, CFO, medical staff coordinator, chief nursing officer, human resources director, emergency department director, and administrative laboratory director during an exit conference performed on 06/27/19.
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 an observation of the frozen section room and interview with the pathology assistant, the laboratory failed to monitor the temperature of the room where materials were stored. Findings include: (1) At the beginning of the survey, the pathology assistant stated to the surveyor the laboratory prepared frozen sections using the Thermoscientific Microm HM 525 Cryostat. The sections were stained with H&E (Hematoxylin & Eosin), then reviewed microscopically by the pathologist; (2) Later during the survey, the surveyor observed one bottle of Surgipath SelecTech Alcoholic Eosin Y 515 stain (lot #071219) stored at room temperature in the frozen section

	room. The manufacturer's storage requirement, as stated on the bottle was 15-30 degrees Centigrade; (3) The surveyor requested room temperature records from January 2019 through the day of the survey. The pathology assistant provided the surveyor with a temperature log with documentation of the room temperature being monitored beginning 06/19/19, and stated to the surveyor the room temperature had not been monitored prior to 06/19/19.
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 and interview with the pathology assistant, the laboratory failed to perform the manufacturer's required maintenance procedures on the cryostat. Findings include: (1) At the beginning of the survey, the pathology assistant stated to the surveyor the laboratory prepared frozen sections using the Thermoscientific Microm HM 525 Cryostat. The sections were stained with H&E (Hematoxylin & Eosin), then reviewed microscopically by the pathologist; (2) The surveyor reviewed the manufacturer's instructions for performing maintenance procedures on the cryostat. Section 5 titled, "Maintenance and Care of the Cryostat" stated the following: (a) Section 5-1 "Shutting-Off For Cleaning" stated, "It is recommended to shut the instrument off every 6-8 weeks"; (b) Section 5-3 "Cleaning and Care of the Microtome" stated, "After each shutting-off or cleaning of the cryostat, the cross roller bearing should be lubricated". (3) The surveyor requested maintenance records for the cryostat from January 2019 through the day of the survey. The pathology assistant provided the surveyor with a maintenance log with documentation of the lubrication performed on 06/19/19 and stated the following to the surveyor: (a) The laboratory's policy was to shut-off the cryostat on a monthly basis; (b) Although the laboratory performed the lubrication procedure as stated in Section 5-3 of the instructions after each monthly shut-off, the procedure had not been documented as performed until 06/19/19. (4) Since the lubrication procedure had not been documented as performed, the surveyor could not verify it had been performed prior to 06/19/19.