Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0641487	01/03/2019
Name of Provider or Supplier	**Street Address, City, State**	
Cytopath Inc	1004 First Street North, Suite 200, Alabaster, AL	

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
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 lack of 2018 room temperature/humidity records, a review of the environmental requirements in the Tissue Tek Cryostat Operator's Manual and an interview with the Corporate Laboratory Manager, the surveyor determined the laboratory failed to monitor and document room temperature and humidity within the laboratory each day the cryostat was used for frozen section processing of patient specimen for eleven months in 2018. The findings include: 1. A review of the operational environmental requirements in the Tissue Tek Cryostat Operator's Manual revealed room temperature should be in the range of 15-28 degrees Celsius, and humidity should be 15-85 percent. 2. A review of the laboratory's records revealed room temperature and humidity were monitored in 2017; these records were reviewed during the previous survey. However, when the surveyor requested the 2018 room temperature and humidity records, these parameters were not monitored until mid-December 2018. There were no records for January thru November 2018. 3. During an interview on 1/3/2019 at approximately 3:00 PM, the Corporate Laboratory Manager was asked why the laboratory had not monitored and documented room temperature/humidity records for most of 2018. The Manager explained that after a new corporate group acquired the laboratory in January 2018, use of the Panther was discontinued. Staff had previously monitored room temperature/humidity because it

	was required for the Panther, however they had not realized the Tissue Tek Cryostat also had operational environmental requirements. Thus the above noted findings were confirmed. .
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 a lack of documentation for the daily slide control quality, and interviews with the Laboratory Director and the Corporate Laboratory Manager, the surveyor determined the laboratory failed to assess and document the slide stain quality each day of patient testing for six out of twelve months in 2018. The findings include: 1. A review of the Histopathology records revealed no documentation of the daily slide stain quality after 1/15/2018. Documentation of the daily slide stain quality control (QC) did not resume until 7/13/2018. 2. During an interview on 1/3/2019 at approximately 3:00 PM, the Laboratory Director and the Corporate Laboratory Manager were asked about the missing months of slide QC. The Laboratory Director explained a new corporate group acquired the laboratory in January 2018, and she had been told the local owning entity would perform the specimen processing and all the QC and Quality Assurance procedures. The Corporate Laboratory Manager then explained there had been a lapse in communication, and she had not been informed of her responsibilities at the newly acquired laboratory until March 2018. 3. As the interview continued on 1/3/2019 at approximately 3:05 PM, the surveyor explained, it is the responsibility of the testing personnel (i.e. the Director or other Pathologists performing the reading) to assess and document the slide QC each day of patient testing. Thus the above noted findings were confirmed. SURVEYOR ID #32558 Licensure and Certification Surveyor