Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D1027743	03/01/2019
Name of Provider or Supplier	**Street Address, City, State**	
Heartland Pathology, Pa	9300 East 29th St North, Suite 208, Wichita, KS	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on observation, review of the procedure manual, 2017, 2018 proficiency testing (PT), 1 of 1 patient record, and interview with the laboratory director and the general supervisor, the laboratory failed to enroll in an approved proficiency testing program for the cell identification/white blood cell (WBC) differential analyte in the specialty of hematology. Findings: 1. Observation of the laboratory revealed Giemsa Wright stain for staining peripheral smears. 2. Review of the procedure manual showed a policy for "Slide Review and Manual Differential". 3. Review of l of 1 patient record showed results for manual differential. 4. Review of proficiency records from 2017 to date March 1 , 2019, revealed a lack of enrollment for white blood cell identification /WBC differential analyte. 5. Interview with the laboratory director and general supervisor on March 1, 2019 at 12:00 PM, confirmed the laboratory performed 82 cell identification/white blood cell manual differential counts for 2018 and failed to enroll in an approved PT program.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100

	Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on observation and interview, the laboratory failed to provide a safe environment for employees (refer to D3011).
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation of 7 of 7 laboratory staff, the pathology processing room and interview with laboratory staff, the laboratory failed to provide a safe environment in which employees are protected from chemical and biological hazards. Findings: 1. Observation of 7 of 7 laboratory staff showed no laboratory personnel wearing formaldehyde monitoring badges. 2. Observation of the pathology processing room showed one Tissue Tek stainer , one Tissue Tek processor, one Tissue Tek SCA coverslip analyzer, and one stainer with a small hood. 3. Observation of the room by the two CLIA surveyors resulted in the CLIA surveyors having to exit the room within 10 minutes due to nausea, headache and dizziness from the strong fumes. 4. Interview with laboratory staff on March 1, 2019 at 9:30 AM confirmed staff has sinus issues , headaches and dry eye symptoms. 5. Interview with the general supervisor on March 1, 2019 revealed testing personnel (A) had the formaldehyde badge sent into StatLab on December 14, 2018 and had a high result of 0.94 ppm.. 6. Interview wit the laboratory director and owners on March 1, 20 19 at 1:30 PM confirmed testing personnel (A) had a high result on the formaldehyde monitoring badge, the 2 CLIA surveyors experienced an immediate reaction to the fumes within the processing room and confirmed the laboratory failed to provide a safe environment in which employees are protected from chemical and bi logical hazards.
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 observation, review of the manufacturer's inserts and interview with laboratory staff, the laboratory failed to monitor and document the humidity and temperature of the rooms used to store reagents and process tissue samples. Findings: 1. Observation of 4 of 4 rooms used to store reagents, gross and process tissue samples showed a lack of room temperature and humidity documentation. 2. Review of the manufacturer's product inserts for Cancer Diagnostic dye reagent for marking tissue samples revealed to store the dye at 59-86 degrees Fahrenheit. 3. Review of the microtome cryostat procedure manual revealed the acceptable operating temperature range is 5-40 degrees Celsius with maximum relative humidity of 60 percent. 4. Interview with laboratory staff and the laboratory director on March 1, 2019 at 2:00 PM confirmed the laboratory failed to monitor and document the room temperature and humidity.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation of reagent material, review of procedure and interview with the laboratory director, the laboratory failed to use non expired reagents for histopathology. Findings: l. Observation of the tissue grossing room revealed the following expired Cancer Diagnostics reagents: two bottles of black dye with an expiration date of 9/20l8 two bottles of red dye with an expiration date of 5/2018 two bottles of orange dye with an expiration date of 7/2018 one bottle of yellow dye with an expiration date of l/2018 2. Observation of the reagents in the grossing room revealed 2 unopened and one opened bottles of Clotest control type III with an expiration date of 5/21/2017. 3. Observation of the reagents in the processing room revealed the following expired reagents: one bottle of 80 percent alcohol with an expiration date of 1/2017 one bottle of 95 percent alcohol with no open date one bottle of Giemsa stain with an expiration date of 12/2015 one bottle of Giemsa stain with no open date one bottle phosphatebuffer with an expiration date of 6/2015 one bottle Hemacolor solution with an expiration date of 1/2013 4. Review of the procedure for Reagents and Solutions showed "reagents and solutions must be labeled to indicate: identity and strength, preparation and expiration date, recommended storage requirements, NFPA code, and other pertinent information." 5. lnterview with the laboratory director on March 1, 2019 at 2:00 PM confirmed the laboratory failed to use non expired reagents and supplies.
D6167	CYTOTECHNOLOGIST RESPONSIBILITIES CFR(s): 493.1485(c) The cytotechnologist is responsible for documenting the number of hours spent examining slides in each 24-hour period. This STANDARD is not met as evidenced by:

	Based on review of Pap Smear documentation revealed and interview with the laboratory director on March 1, 2019 at 2:00 PM confirmed 4 of 4 testing personnel failed to document the total number of hours spent examining Pap smear slides, in a 24 hour period.