Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0442057	05/10/2018
Name of Provider or Supplier	**Street Address, City, State**	
Heartland Laboratory	221 S Main St, Chaffee, MO	

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, proficiency testing(PT) and patient records, and interview with the laboratory director, the laboratory failed to enroll in an approved proficiency testing program for the acid fast bacilli (AFB) analyte in the subspecialty of mycobacteriology and cell identification/white blood cell differential(WBC) analyte in the speciality of hematology since 2000. Findings: 1. Observation of the laboratory revealed a kit for acid fast bacilli staining and Dipp Kwik stain kit for staining peripheral smears. 2. Review of the procedure manual showed a policy for "AFB- direct smears" and a policy for "Dipp Kwik staining for peripheral smears and fixed tissue staining." 3. Review of 2 of 2 patient records showed reports for AFB stain and cell identification/WBC manual differential. 4. Review of proficiency records from 2000 to date May 10, 2018, revealed a lack of enrollment for acid fast bacilli analyte and cell identification/WBC differential analyte. 5. Interview with the laboratory director on May 10, 2018 at 12:00 PM, confirmed he performed cell identification/white blood cell manual differential counts and acid fast bacilli stains and failed to enroll in an approved PT program.
D5401	PROCEDURE MANUAL

	CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of "daily procedure" for flotation bath and interview with the laboratory director the laboratory failed to follow procedure for temperature of flotation bath for 89 of 89 days from January 1, 2018 to present day. Findings: 1. Review of "daily procedure" for flotation bath states "sections are placed on the 42 degree centigrade water in the flotation bath." 2. Review of flotation bath temperature log shows acceptable temperature range as 37 degrees C +/- .5 degrees C. 3. Review of temperature log for flotation bath shows 89 days of temperature not with in acceptable range stated in procedure. 4. Interview with the laboratory director on May 10, 2018 at 12:15 PM confirmed the laboratory failed to follow procedure for temperature of flotation bath.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observation of histopathology staining reagents and interview with laboratory director the laboratory failed to follow manufacturer's instructions in storage of Periodic Acid Solution. Findings: 1. Observation of Periodic Acid Solution lot # 41091 expiration 11/18 showed solution should be stored at 2 degrees C to 8 degrees C. Laboratory stored Periodic Acid Solution at room temperature (20 degrees C). 2. Observation of Periodic Acid Solution .5% lot # 40531 expiration 9/18 showed solution should be stored at 2 degrees C to 8 degrees C. Laboratory stored Periodic Acid Solution at room temperature (20 degrees C). 3. Interview with the laboratory director on May 10, 2018 at 12:15 PM confirmed laboratory failed to follow manufacturer's instructions for the storage of Periodic Acid Solution.
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 2 of 2 rooms used to store reagents 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 Leica RM 2125 microtome procedure manual revealed the acceptable operating temperature range is 10-35 degrees Celsius with maximum humidity of 80 percent. 4. Interview with laboratory staff and the laboratory director on May 10, 2018 at 12:00 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 dye reagent material and interview with the laboratory director, the laboratory failed to use non expired dye reagent for histopathology. Findings: 1. Observation of the tissue processing room revealed the following expired Cancer Diagnostics reagents: one bottle of green dye with an expiration date of 1 /2018 one bottle of violet dye with an expiration date of 2/2017 one bottle of blue dye with an expiration date of 1/2018 one bottle of black dye with an expiration date of 12 /2017 one bottle of red dye with an expiration date of 12/2017 one bottle of orange dye with an expiration date of 8/2017 one bottle of yellow dye with an expiration date of 10/2017 2. Interview with the medical director on May 10, 2018 at 12:00 PM confirmed the laboratory failed to use non expired reagents and supplies.
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 review of microscope maintenance and interview with the laboratory director on May 10, 2018 at 12:00 PM the laboratory failed to perform and document maintenance on the microscope for 2017 and to date May 10, 2018.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a

	function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on observation, review of maintenance documentation, and interview with the laboratory director, the laboratory failed to define and perform a function check protocol to verify the accuracy of the incubator temperature, two of two ventilation hoods, one Leica 1215 waterbath, one Leica microtome and one Leica tissue processor. Findings: 1. Observation of two tissue processing rooms showed two ventilation hoods used to process slides with hazardous chemicals, one Leica 2125 microtome, one Leica tissue processor, one Leica 1215 waterbath and one incubator. 2. No documentation was found to show the laboratory defined or performed a function check protocol to verify the accuracy of the temperature of the incubator, the function of two of two ventilation hoods, one Leica microtome, Leica 1215 waterbath and Leica tissue processor. 3. Interview with the laboratory director on May 10, 2018 at 12:00 PM confirmed, the laboratory failed to define a protocol and perform a function check to verify the accuracy of the function of two ventilation hoods used to process slides with hazardous chemicals, one Leica 2125 microtome, one Leica tissue processor, one Leica 1215 waterbath, and one incubator,