Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D0692147	10/13/2020
Name of Provider or Supplier	**Street Address, City, State**	
First Choice Immediate Care Mcreary	1900 North Hwy 27, Whitley City, KY	

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 record review and staff interview on 10/13/2020, the laboratory failed to monitor and document room temperature and humidity to ensure manufacturer's temperature requirements were met for the operation of the Beckman Coulter AcT Diff hematology instrument from 08/08/2019 through 10/12/2020. Findings include: Review of the manufacturer's operations manual under 4.1 Instrument Specifications stated Temperature, Ambient Operating range of 16 degrees Centigrade to 35 degrees Centigrade (61 degrees Fahrenheit to 95 degrees Fahrenheit) and Humidity range of 20 percent to 85 percent without condensation. Review of temperature logs failed to reveal recordings of room temperature and humidity from the date of installation of the hematology instrument on 08/08/2019 through 10/12/2020. Testing personnel acknowledged in an interview at 11:00 AM on 10/13/2020, the laboratory failed to follow the manufacturer's requirements for monitoring room temperature and humidity for the operation of the Beckman Coulter AcT Diff hematology instrument.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of

	the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on record review and staff interview on 10/13/2020, the laboratory director failed to review and evaluate the verification procedures used to determine the precision, accuracy, reportable ranges, and reference (normal) ranges for the Complete Blood Count (CBC) analytes reported on the Beckman Coulter AcT Diff Hematology analyzer prior to reporting patient results. Findings include: Record review revealed the AcT Diff hematology instrument was installed 08/08/2019. Record review revealed patient samples were tested and results reported 08/09/2019. Record review failed to reveal documentation of evaluation and approval of the verification procedures prior to patient testing. An interview with Testing Personnel at 11:00 AM on 10/13/2020, revealed the Laboratory Director failed to review, evaluate, and approve the verification procedures on the AcT Diff Hematology instrument prior to reporting CBC analyte results