Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D2029828	05/10/2019
Name of Provider or Supplier	**Street Address, City, State**	
Dr Hinkebein, Davis, Mccormick Pllc	9811 Brownsboro Road, Suite 101, Louisville, 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 staff interview and record review on May 10, 2019, the laboratory failed to monitor and document the humidity in the laboratory where the testing was performed. Humidity was not recorded from July 19, 2017 through May 9, 2019. Findings include: 1. The Manufacturer's operations manual for the Cell Dyn Emerald analyzer lists an operating range for humidity for the anayzer between Zero percent (0%) and eighty percent (80%). 2. Review of Maintenance log revealed no documented evidence the humidity had been monitored and recorded from July 19, 2017 through May 9, 2019. 3. Testing personnel acknowledged in an interview at 10: 48AM on May 10, 2019, the laboratory director failed to have a system in place to ensure the humidity was monitored and documented daily.