Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0927122	(X3) Date Survey Completed 12/17/2019
Name of Provider or Supplier Vaseem Moulana Md Psc	**Street Address, City, State** 1240 Woodland Drive, Elizabethtown, 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 12/17/2019, the laboratory failed to ensure humidity readings were consistent with manufacturer's specifications in the operation of the SYSMEX XP-300 hematology analyzer twenty-three (23) of thirty-one (31) days of patient testing from 11/01/2019 through 12/17/2019. Findings include: 1. The Manufacturer's operations manual for the SYSMEX XP-300 analyzer lists an operating range for humidity thirty percent (30%) to eighty-five percent (85 %). 2. Review of temperature logs for humidity revealed readings less that 30% on 11 /04, 11/08, 11/11, 11/12/, 11/13, 11/14, 11/15, 11/18, 11/19, 11/20, 11/21, 11/25, 11 /26, 12/02, 12/03, 12/04, 12/05, 12/06, 12/11, 12/12, 12/13, 12/16, and 12/17/2019. 3. Testing personnel acknowledged in an interview at 11:30 AM on 12/17/2019, the laboratory failed to have a system in place to ensure humidity was monitored and readings were consistent with manufacturer's specifications.