Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0690634	(X3) Date Survey Completed 05/16/2018
Name of Provider or Supplier Harrison Family Practice Clinic - Washington Reg	**Street Address, City, State** 715 West Sherman Suite G, Harrison, AR	

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: Through observation, review of manufacturer's instrument manual, lack of documentation, and interview it was determined that the laboratory failed to document humidity levels required for proper instrument operation. Findings follow: A: The manufacturer's instrument manual for the Celldyne 1800 hematology analyzer states that ambient humidty requirement for proper instrument operation is 10% to 85%. B: Upon request, the laboratory could not produce records of humidity measurements for 2017 and 2018. C: In an interview on 05/16/18 at approximately 1115 the technical consultant identified as number 2 on the CMS 209 form verified that the laboratory does not monitor or document humidity levels.