Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0469021	06/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
Millard Henry Clinic	1601 North Church, Atkins, 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 operation manual, lack of documentation and interview it was determined that the laboratory failed to monitor ambient humidity in one of one rooms in which instruments with a required operational humidity range were used. Findings follow: 1. In an initial tour of the laboratory on 6/26/18 at approximately 10:00 AM a Sysmex XP-300 hematology analyzer was observed. 2. Review of the manufacturer's operation manual for the Sysmex XP-300 analyzer revealed an operational humidity requirement of 30% to 80%. 3. Upon request, the laboratory could not produce humidity measurement records for the room in which the Sysmex XP- 300 hematology was located. 4. In an interview on 6/26/18 at approximately 02:15 PM, the technical consultant identified as number 2 on the CMS 209 form confirmed that the Sysmex XP-300 hematology analyzer is used to perform CBC analysis and humidity levels were not monitored and documented.
D6005	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c) 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. (c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed. This STANDARD is not met as evidenced by: Through review of API proficiency testing documents and interview it was determined that the laboratory director failed to sign proficiency testing attestation forms in eight of eight proficiency testing events reviewed. Findings follow: 1. Review of proficiency testing documents for three events of API Hematology /Coagulation proficiency testing in 2017, three events of API Microbiology proficiency testing in 2017. one event of Hematology/Coagulation proficiency testing in 2018, and one event of API Microbiology proficiency testing in 2018 revealed that in all of the events reviewed the laboratory director's name was signed by the testing personnel on the events' attestation forms. 2. Upon request, the laboratory could not produce documentation that the laboratory director had delegated signature authority for the attestation forms to any laboratory personnel. 3. In an interview on 2/26/18 at approximately 02:00 PM, the technical consultant identified as number 2 on the CMS 209 form confirmed that the testing personnel had signed the laboratory director's name on the proficiency testing attestation form and that the laboratory director had not signed a delegation of authority to sign attestation forms for any laboratory personnel.