Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2099298	03/28/2018
Name of Provider or Supplier	**Street Address, City, State**	
Community Clinic Fayetteville Medical	3162 W Martin Luther King Blvd, Fayetteville, 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 review of instrument manufacturer's manuals, laboratory humidity records, and interview it was determined that the laboratory failed to monitor humidity in one of one room in which an intrument with operating humidity requirement was used. Findings follow: A. Review of the instrument manufacturer's manual for the Emerald hematology analyzer revealed that the instrument had an operating humidity requirement of less than 80%. B. Review of laboratory humidity records revealed that on 58 of 58 days in January, February, and March of 2018, in which the laboratory was open, humidity level was recorded as 67% with no variation. C. On a tour of the laboratory on 3/28/18 at approximately 1130 the hygrometer was observed with a reading of 67% with a sub-script stating "MAX". D. Review of the manufacturer's users manual for the hygrometer revealed that if the hygrometer had a subscript of "MAX" that it was displaying the maximum humidity level since the instrument was last set and that the re-set button had to be pressed again to see the current humidity level. E. On the tour, the instrument was re-set, the "MAX" subscript disappeared and the hygrometer displayed a humidity level of 54%. F. In an interview on 3/28/18 at approximately 1145, the laboratory director identified as number one on the CMS 209

	form confirmed that the hygrometer had not been used according to the manufacturer's instructions and humidity records for 2018 could not be considered accurate.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Through review of personnel records, lack of documentation, and interview it was determined that the laboratory failed to have written authorization to perform testing for six of six testing personnel listed on the CMS 209 form. Findings follow: A. Upon review of personnel records, no written authorization to test was found for testing personnel identified as numbers two through seven inclusive on the CMS 209 form. B. Upon request, the laboratory could not produce a written authorization to test for the personnel mentioned above. C. In an interview on 3/28/18 at approximately 1145 the laboratory director identified as number 1 on the CMS 209 form confirmed that no written authorization to test was available for the testing personnel identified as numbers two through seven inclusive on the CMS 209 form and that those personnel did perform moderate complexity testing.