Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0465341	06/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Family Clinic Of Ashley County Pa	909 Unity Road, Crossett, 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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: . Through observations made during a tour of the laboratory, as well as interview with staff, it was determined the laboratory had BD Vacutainer Red Top blood collection tubes available for use when they had exceeded their expiration date. As evidenced by: A. During a tour of the laboratory on 06/20/2018 at 10:30, the Surveyor observed 56 of 56 BD Vacutainer Red Top blood collection tubes located in a upper shelf within the laboratory with an expiration date of 3/31/2018. The tubes were available for use when they had exceeded their expiration. B. In an interview on 06/20/2018 at 10:30, testing personnel #7 (as listed on form CMS-209) confirmed the expiration dates and the vacutainer collection tubes were available for use.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

	This STANDARD is not met as evidenced by: . Through observations made during a tour of the laboratory, lack of documentation, as well as interviews with staff, it was determined the laboratory failed to perform function checks on the centrifuge used for processing patient samples. As evidenced by: A. During a tour of the laboratory on 6/20/2018 at 10:30, the laboratory centrifuge was observed with documentation of centrifuge function checks dated 12/17/2015. B. The surveyor requested documentation of centrifuge function checks performed for 2016 and 2017 none was provided. C. In an interview on 06/20/2018 at 1045, laboratory employee #7 (as listed on the form CMS-209) confirmed that the centrifuge function checks had not been performed for 2016 and 2017.
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 a review of personnel files, lack of documentation, and interviews with staff, it was determined the laboratory failed to have written authorization to perform testing for one of twelve testing personnel (as listed on CMS-209). As evidenced by: A. Upon review of training documentation for twelve of twelve laboratory testing personnel, testing personnel #9 (as listed on Form CMS 209) was trained to perform moderate complexity testing. B. Upon reviewed of personnel records for twelve of twelve laboratory testing personnel, testing personnel #9 (as listed on form CMS 209) personnel record did not include a signed authorization to perform moderate complexity testing by the Laboratory Director. C. In an interview at 1100 on 06/20 /2018, testing personnel #7 (as listed on the form CMS-209) confirmed there was no written authorization to perform moderate complexity testing for testing personnel #9 signed by the Laboratory Director.