Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0465341	12/02/2022
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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: . Through review of laboratory policy and procedure, observation and interview it was determined that the laboratory failed to label one of one urine specimen according to their specimen collection policy. Survey Findings follow: A. A review of the laboratory policy and procedure manual revealed the urine collection procedure " Collection containers must be clean and made of inert disposable plastic. The container must have a label that will adhere under refrigeration. The label must include the patient's name, date, and time of collection." B. During a tour of the laboratory on 12/2/2022 at 12:30 p.m., one unlabeled urine specimen was observed in the laboratory available for testing. C) In an interview on 12/2/2022 at 12:30 p.m. , the laboratory director confirmed that the urine specimen was unlabeled and available for testing.
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 CMS form 209, personnel records for six of six testing personnel, lack of documentation, and interviews with laboratory staff, it was determined the laboratory director failed to specify, in writing, which examinations and procedures each individual was authorized to perform and whether supervision was required. Survey findings follow: A. A review of CMS form 209 revealed the names of six laboratory testing personnel performing moderate complexity testing. B. A review of personnel records revealed there were no signed authorizations to perform moderate complexity testing for six of six testing personnel listed on the form CMS-209. D. Upon request, the laboratory could not provide signed authorizations for testing personnel listed on CMS form 209 to perform moderate complexity testing. F. In an interview at 11:30 a.m. on 12/02/2022, the laboratory director confirmed there was no written authorization stating which tests the testing personnel (# 1 thru # 6) on the CMS form 209 are authorized to perform.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: . Through review of the laboratory policy manual, personnel records, lack of documentation, and interview with staff, it was determined that the technical consultant failed to document personnel competency for one of six personnel identified on the CMS form 209. Survey findings follow: A. A review of personnel records for testing personnel revealed that the technical consultant failed to perform an semiannual competency evaluation for testing personnel #2 (as listed on form CMS 209) who was hired March 2022. B. Upon request, the laboratory could not provide competency evaluations for the personnel identified above. C. In an interview on 12/2 /2022 at 10:30 a.m., the technical consultant confirmed that an initial or a six-month competency evaluation had not been performed on testing personnel #2 (as listed on form CMS 209).