Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0946993	09/23/2020
Name of Provider or Supplier	**Street Address, City, State**	
Fountain Lake Family Medicine	4517 Park Avenue, Hot Springs, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: . Based on review of personnel records, lack of documentation and interviews, it was determined that the competency of two of eleven laboratory personnel was not assessed by the laboratory director. Survey Findings Follow: A. A review of personnel records for eleven of eleven laboratory personnel revealed that there was no documentation of the annual competency evaluation for the technical consultant in 2019, and laboratory personnel #11 (as listed on CMS form 209) for 2019 and 2020. B. Upon request the laboratory could not provide documentation of annual competency for the technical consultant for 2019 or laboratory personnel #11 (as listed on CMS form 209) for 2019 and 2020. C. In an interview on 9/23/2020 @ 10:30 the technical consultant confirmed that there was no assessment of competency by laboratory director for the technical consultant and laboratory personnel #11 (as listed on CMS form 209).
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 eleven of eleven laboratory personnel, 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 eleven laboratory testing personnel performing moderate complexity testing. B. A review of personnel records revealed there were no signed authorization to perform moderate complexity testing for one of eleven (laboratory personnel #11) testing personnel listed on the form CMS-209. C. Upon request, the laboratory could not provide signed authorization for testing personnel #11 (as listed on CMS form 209) to perform moderate complexity testing. D. In an interview at 10:00 a.m. on 9/93/2020, the technical consultant confirmed there was no written authorization from the laboratory director stating which tests the testing personnel #11 (as listed on CMS form 209) is authorized to perform.