Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0463919	11/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
Family Doctors	8383 Millicent Way, Shreveport, LA	

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
D0000	A CERTIFICATION SURVEY was performed at The Family Doctors - CLIA # 19D0463919 on November 19, 2018. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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: **REPEAT DEFICIENCY** Based on observation and interview with personnel, the laboratory failed to ensure supplies have not exceeded their expiration date. Findings: 1. Observation by surveyor during laboratory tour on November 19, 2018 revealed the following expired items in the Phlebotomy Room: * Phlebotomy area - cabinet on 2nd shelf a) Griener Bio-one Vacuette 3mL Lithium Heparin Sep Lot B170836Q, Exp 10 /24/18, Quantity 1 tube b) BD Vacutainer 6mL Trace Element Serum (Blue) Lot 6343851, Exp 12/31/17, Quantity 3 tubes c) BD Vacutainer Trace Element K2 EDTA (Purple) Lot 616925, Exp 6/17, Quantity 2 tubes * Phlebotomy Area - cabinet below centrifuges a) Fisher Finest Bacteriology Culture Collection and Transport System (Fisher Healthcare) Lot 6F02A, Exp 12/2/17, Quantity 1 bag (50 swabs) b) Therno Scientific Versa TREK REDOX 2 8mL anaerobic Blood Culture bottles Lot 226502, Exp 10/18, Quantity 2 bottles * Phlebotomy Area - Draw station a) BD Vacutainer K2 EDTA 2mL (purple) Lot 7097854, Exp 7/31/18, Quantity 6 tubes 2. In interview on November 19, 2018 at 2:42 pm, Personnel 2 stated she was unaware that tubes were expired in the phlebotomy rack in place for patient collection. Personnel 2 further stated that the tubes were used only for short draw samples and they are rarely used except for Hemoglobin A1C testing. 3. In further interview on November 19, 2018 at

	2:50 pm, Personnel 2 stated she was unaware that some of the supplies were expired in the Phlebotomy area. Personnel 2 confirmed the above items were expired.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the laboratory failed to perform corrective actions when the cuvette temperature failed to be within acceptable range as required by the manufacturer for the Siemens Dimension EXL 200 Chemistry analyzer. Findings: 1. Observation by surveyor during laboratory tour on November 19, 2018 revealed the laboratory utilized the Siemens Dimension EXL 200 analyzer for chemisty testing. 2. Review of the Siemens Dimension EXL 200 analyzer maintenance logs revealed the acceptable cuvette temperature range as 36.8 to 37.2 degrees Celsius. 3. Further review of the maintenance logs revealed the laboratory did not take corrective action when the cuvette temperature was out of range for the following three (3) days reviewed from January 1, 2018 through November 19, 2018: a. October 24, 2018 - temperature recorded as 37.3 degrees celsius b. October 29, 2018 - temperature recorded as 37.3 degrees celsius c. November 1, 2018 - temperature recorded as 37.3 degrees celsius 4. In interview on November 19, 2018 at 5:00 pm, Personnel 2 stated the laboratory does not have a policy for corrective action when cuvette temperature is not within the acceptable range. Personnel 2 confirmed the laboratory did not perform corrective action for the dates above.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory's Quality Assurance monitors failed to identify and correct quality issues. Findings: 1. The laboratory failed to ensure supplies have not exceeded their expiration date. Refer to D5417. 2. The laboratory failed to perform corrective actions when the cuvette temperature failed to be within acceptable range as required by the manufacturer for the Siemens Dimension EXL 200 Chemistry analyzer. Refer to D5781.

D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel were performing test methods as required for accurate and reliable results. Refer to D5417.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation, record review and interview with laboratory personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Refer to D5793.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D5781.