Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0463919	02/28/2023
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 Recertification survey was performed at The Family Doctors, CLIA ID # 19D0463919, on February 28, 2023. The Family Doctors was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1250 CONDITION: Analytic systems 42 CFR 493.1403 CONDITION: Laboratories Performing Moderate Complexity Testing, Laboratory Director
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing results and interview with personnel, the laboratory failed to successfully verifiy the accuracy of 25-OH Vitamin D for two (2) of four (4) consecutive proficiency testing events. Findings: 1. Review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) results from 2022 and 2023 revealed the laboratory received the following scores in two (2) of four (4) events reviewed: a) 2022 Chemistry Core 3rd event: score of 50% b) 2023 Chemistry Core 1st event: score of 0% 2. In interview on February 28, 2023 at 9:59 am, Technical Consultant 2 stated the laboratory received the scores for Vitamin D and opted to cease testing pending two (2) consecutive passing events. Technical Consultant confirmed the identified scores for proficiency testing results.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that

	provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation by surveyor, review of laboratory policies and records as well as interview with personnel, the laboratory failed to ensure the quality of testing within the analytic systems. Findings: 1. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401 I. 2. The laboratory failed to follow their established policy to perform water cultures monthly for six (6) of twelve (12) months reviewed in 2022. Refer to D5401 II. 3. The laboratory failed to ensure complete verification of performance studies for the Siemens Dimension EXL 200 chemistry analyzer. Refer to D5421 I. 4. The laboratory failed to ensure complete verification of performance studies for the Sysmex XN-530 Hematology analyzer. Refer to D5421 II. 5. The laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the analytic system. Refer to D5791.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's policies and interview with personnel, the laboratory failed to establish a complete policy and procedure manual. Findings: 1. Review of the laboratory's policies revealed the laboratory did not have written policies and procedures that included the following: a) Performance specification: detailed procedures for performing accuracy and precision (day-to-day, run-to-run, and within-run, as well as, operator variance), reportable and reference range studies, and actions to take when data from the studies fail to meet acceptability criteria 2. In interview on February 28, 2023 at 10:02 am, Technical Consultant 2 confirmed the laboratory did not include the above identified policy. II. Based on review of laboratory policy and records as well as interview with personnel, the laboratory failed to follow their established policy to perform water cultures monthly for six (6) of twelve (12) months reviewed in 2022. Findings: 1. Review of the laboratory policy "Monthly Millipore Sample Collection fo Contamination" revealed "Monthly a water sample must be submitted to the reference laboratory to make sure the water system does not contain bacterial contamination". 2. Review of laboratory records for water purification revealed the laboratory did not perform a monthly water culture for the following six (6) of twelve (12) months reviewed in 2022: a) February 2022 b) April 2022 c) May 2022 d) June 2022 e) July 2022 f) September 2022 3. In interview on February 28, 2023 at 12:50 pm, Technical Consultant 2 confirmed the laboratory did not perform monthly water cultures as required by laboratory policy.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system

	must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: I. Based on observation by surveyor, review of laboratory policy and performance specification studies as well as interview with personnel, the laboratory failed to ensure complete verification of performance studies for the Siemens Dimension EXL 200 chemistry analyzer. Findings: 1. Direct observation by surveyor during the laboratory tour on February 28, 2023 at 9:15 am revealed the laboratory utilizes the Siemens Dimension EXL 200 analyzer for the following chemistry tests: Glucose, Blood Urea Nitrogen, Creatinine, Calcium, Sodium, Potassium, Chloride, Alkaline Phosphatase, Alanine Transaminase, Aspartate Aminotransferase, Total Bilirubin, Total Protein, Albumin, Carbon Dioxide, Thyroid Stimulating Hormone, Free Thyroxine, Total Thyroxine, Microalbumin, Prostate Specific Antigen, Creatine Kinase, Hemoglobin A1C 2. Review of the laboratory's policy manual revealed the laboratory did not have a policy for performance specification studies. 3. Review of the laboratory's performance studies for the Siemens Dimension EXL 200 analyzer revealed the laboratory did not have documentation for the following: a) Complete precision to include Day to Day and Operator Variance with raw data to support studies b) Reportable Range to include raw data to support c) Reference Range to include pertinent information to support d) Acceptability criteria e) Laboratory Director approval 4. In interview on February 28, 2023 at 10:02 am, Technical Consultant 2 confirmed the laboratory did not have complete performance studies for the Siemens Dimension chemistry analyzer. II. Based on observation by surveyor, review of laboratory policy and performance specification studies as well as interview with personnel, the laboratory failed to ensure complete verification of performance studies for the Sysmex XN-530 Hematology analyzer. Findings: 1. Direct observation by surveyor during the laboratory tour on February 28, 2023 at 9:15 am revealed the laboratory utilizes the Sysmex XN-530 analyzer for Complete Blood Count (CBC) testing. 2. Review of the laboratory's policy manual revealed the laboratory did not have a policy for performance specification studies. 3. Review of the laboratory's performance studies for the Sysmex XN-530 analyzer revealed the laboratory did not have documentation for the following: a) Complete precision to include run to run, day to day, within run, and operator variance along with the raw data to support studies b) Reportable Range to include the raw data to support studies c) Reference Range to include pertinent information d) acceptability criteria e) Laboratory Director approval 4. In interview on February 28, 2023 at 10:02 am, Technical Consultant 2 confirmed the laboratory did not have complete performance studies for the Sysmex XN-530 hematology analyzer.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Based on review of laboratory policy and records and interview with personnel, the laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the analytic system. Findings: 1. Review of the laboratory policy and procedures revealed the laboratory has a quality assessment process in place; however, the following deficient practices were not identified: a) The laboratory failed to establish a complete policy and procedure manual. Refer to D5401 I. b) The laboratory failed to follow their established policy to perform water cultures monthly for six (6) of twelve (12) months reviewed in 2022. Refer to D5401 II. c) The laboratory failed to ensure complete verification of performance studies for the Siemens Dimension EXL 200 chemistry analyzer. Refer to D5421 I. d) The laboratory failed to ensure complete verification of performance studies for the Sysmex XN-530 Hematology analyzer. Refer to D5421 II.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on observation by surveyor, review of laboratory policies and records as well as interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure performance verification studies were complete. Refer to D6013. 2. The Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D6014. 3. The Laboratory Director failed to ensure that a complete quality assessment (QA) program was established to assure the quality of laboratory services provided. Refer to D6021. 4. The Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D6030. 5. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D6031.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on observation by surveyor, review of laboratory policy, performance studies, and interview with personnel, the Laboratory Director failed to ensure performance verification studies were complete. Findings: 1. The laboratory failed to ensure complete verification of performance studies for the Siemens Dimension EXL 200

	chemistry analyzer. Refer to D5421 I. 2. The laboratory failed to ensure complete verification of performance studies for the Sysmex XN-530 Hematology analyzer. Refer to D5421 II.
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 review of laboratory policy and records along with interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to successfully verifiy the accuracy of 25-OH Vitamin D for two (2) of four (4) consecutive proficiency testing events. Refer to D5217.
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 by surveyors, review of laboratory records, and interview with personnel, the Laboratory Director failed to ensure that a complete quality assessment (QA) program was established to assure the quality of laboratory services provided. Refer to D5791.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

	This STANDARD is not met as evidenced by: Based on review of personnel records and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Findings: 1. The Technical Consultant failed to evaluate and complete the competency assessments of four (4) of six (6) testing personnel in 2022. Refer to D6046.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on review of laboratory policies and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Findings: 1. The laboratory failed to establish a complete policy and procedure manual. Refer D5401 I. 2. The laboratory failed to follow their established policy to perform water cultures monthly for six (6) of twelve (12) months reviewed in 2022. Refer to D5401 II.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the CMS 209 (Laboratory Personnel Report), personnel records, and interview with personnel, the Technical Consultant failed to evaluate and complete the competency assessments of four (4) of six (6) testing personnel in 2022. Findings: 1. Review of the CMS 209 form provided to surveyor revealed the the following personnel serve as Technical Consultant: a) Personnel 1 (who also serves as Laboratory Director) b) Personnel 3 2. Review of the laboratory's personnel records revealed the following four (4) of six (6) testing personnel did not have documentation of competency assessments performed in 2022: a) Personnel 4 b) Personnel 5 c) Personnel 6 d) Personnel 8 3. In interview on February 28, 2023 at 10: 31 am, Technical Consultant 2 stated that she accepted the position of technical consultant in December 2022 and was not employed during 2022. Technical Consultant 2 confirmed the competency assessments were not completed for the identified testing personnel.