Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0463919	07/21/2021
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 on July 21, 2021 at Family Doctors, CLIA ID # 19D0463919. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: I. Based on observation by surveyor, review of manufacturer's instructions and test menu, as well as interview with personnel, the laboratory failed to include "Fact Sheets" to providers or patients for Emergency Use Authorization (EUA) SARS COV-2 testing. Findings: 1. Observation during the laboratory tour on July 21, 2021 at 10: 08 am revealed the laboratory performs SARS COV-2 testing utilizing the Cepheid Gene Xpert analyzer along with the Xpert Xpress SARS-CoV-2/Flu/RSV test kit. 2. Review of the manufacturer's instructions for use under "Conditions of Authorization for Laboratory and Patient Care Settings" section revealed " Authorized laboratories using your product will include with result reports of the Xpert Xpress SARS-CoV-2 /Flu/RSV test, all authorized Fact Sheet. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media". 3. In interview on July 21, 2021 at 12:40 pm, Personnel 2 confirmed the laboratory was not aware of and does not provide the "Fact Sheets" for the COVID test to providers or patients. II. Based on observation by surveyor, review of manufacturer's quality control package inserts and laboratory quality control records as well as interview with personnel, the laboratory failed to establish its own expected range of responses for Zeptometrix Natrol quality control (QC) material. Findings: 1. Observation by surveyor during laboratory tour on July 21, 2021 at 10:08

	am revealed the laboratory utilizes the Cepheid GeneXpert Xpress analyzer with Zeptometrix Natrol External Run Control for the following tests: a) SARS-CoV-2/Flu /RSV 2. Review of the ZeptoMetrix Corporation NATtrol External Run Controls package insert under "Expected Results" revealed "Each laboratory must evaluate the product and establish their own acceptance criteria". 3. Review of the laboratory's quality control (QC) records revealed the laboratory did not establish its own acceptance criteria for the ZeptoMetrix external control material. 4. In interview on July 21, 2021 at 12:40 pm, Personnel 2 stated she was unaware the Zeptometrix External QC should be established. Personnel 2 confirmed the laboratory uses the responses provided by the manufacturer and does not establish their own.
D2105	ENDOCRINOLOGY CFR(s): 493.843(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and interview with personnel, the laboratory failed to document remedial action for unacceptable Thyroxine proficiency testing scores. Findings: 1. Review of the laboratory's 2020 American Proficiency Institute (API) Proficiency Testing (PT) records revealed the laboratory received the following unacceptable results: a) 2020 Chemistry - Core - 1st event: CH-02, Thyroxine, unacceptable 2. Further review of the 2020 API Proficiency Testing records revealed the laboratory did not have documentation of corrective action, investigation, or remedial action for the unacceptable score. 3. In interview on July 21, 2021 at 12:25 pm, Personnel 2 confirmed remedial action was not taken for the above unacceptable PT score.
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 procedures and interview with personnel, the laboratory failed to have a complete policy and procedure manual. Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory did not include the following: a) Reporting of SARS COV-2 test results to state public health agency, to include but not limited to frequency and who is responsible. 2. In interview on July 21, 2021 at 12:40 pm, Personnel 2 stated she was unaware the laboratory needed a policy for SARS CoV-2 reporting of test results. Personnel 2 confirmed the laboratory did not have the identified policy.

D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of the operator's manual and laboratory's maintenance records as well as interview with personnel, the laboratory failed to ensure yearly maintenance for the Cepheid Gene Xpert Xpress analyzers was performed per manufacturer requirements. Findings: 1. Observation by surveyor during the laboratory tour on July 21, 2021 at 10:08 am revealed the laboratory utilizes three (3) Cepheid Gene Xpert Xpress analyzers. 2. Review of the Cepheid GeneXpert Xpress operator's manual under "Calibrating the Instrument" revealed "Cepheid recommends that the instrument be recalibrated after 1 year of use, based on initial installation date (or based on the previous calibration for subsequent years) or at 2,000 tests per instrument module, whichever comes first". 3. Review of the laboratory's GeneXpert Xpress System Maintenance Log revealed the following maintenance tasks: a) Daily Maintenance: Clean work area, Close all module doors, Discard used cartridges b) Weekly Maintenance: Power down the GeneXpert Xpress instrument, Power down the GeneXpert Xpress Hub c) Monthly Maintenance: Archive tests, Purge tests, Clean/Replace the fan filter d) Quarterly Maintenance: Clean plunger rod and cartridge bays, Clean instrument and Hub surfaces e) Yearly Maintenance: Perform annual instrument maintenance f) As Necessary: Print system log report, Back up database 4. Review of the laboratory's Cepheid maintenance logs from January 2019 through June 2021 for three (3) of three (3) Cepheid GeneXpert Xpress analyzers revealed the laboratory performed the yearly maintenance in January 2019 and January 2021; however, the laboratory did not have documentation of performing the yearly maintenance in January 2020. 5. In interview on July 21, 2021 at 12:40 pm, Personnel 2 confirmed the laboratory did not document the 2020 yearly maintenance for three (3) Cepheid analyzers
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory performed corrective actions for unacceptable proficiency testing results. Refer to D2105
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6)

	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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance. Refer to D5429.
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 record review and interview with personnel, the Laboratory Director failed to ensure an approved policy and procedure manual was available to all personnel. Refer to D5401.