Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0931056	01/14/2020
Name of Provider or Supplier	**Street Address, City, State**	
Family Medicine Center Alexandria	3335 Prescott Rd, Alexandria, 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 on January 14, 2020 at Family Medicine Center, CLIA ID # 19D0931056. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure the Laboratory Director signed the attestation statement for one (1) of six (6) proficiency testing (PT) events reviewed. Findings: 1. Review of the laboratory's American Proficiency Institute (API) proficiency records for 2018 and 2019 revealed the Laboratory Director did not sign the attestation statement for the following event: a) 2019 Hematology/Coagulation 1st Event 2. In interview on January 14, 2020 at 3: 20 pm, Personnel 2 stated that she must have overlooked the attestation statement when having the Laboratory Director review proficiency event. Personnel 2 confirmed the Laboratory Director did not sign the attestation statement for the above event.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(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 record review and interview with personnel, the laboratory failed to document remedial action for unacceptable Chemistry scores. Findings: 1. Review of the laboratory's 2018 and 2019 Proficiency Testing (PT) results revealed the laboratory received the following unacceptable results: a) 2018 Chemistry - Core - 1st Event: CH-01 ALT/SGPT 80% 2. Further review of PT records revealed the laboratory did not have any documentation of corrective action, investigation, or remedial action of the unacceptable scores. 3. In interview on January 14, 2020 at 3: 20 pm, Personnel 2 stated the laboratory did not investigate the PT result since it was considered a passing event at 80%.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Refer to D2009.
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 followed the corrective action plan for unacceptable proficiency testing results. Refer to D2094.