Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0931056	02/14/2018
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 conducted on February 14, 2018 at Family Medicine Center-CLIA ID # 19D0931056. Family Medicine Center laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard 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: Based on observation and record review, the laboratory failed to report Urine Drug Screen (UDS) test results as preliminary results and failed to confirm all UDS test results as required by the manufacturer. Findings: 1. Observation by the surveyor on February 14, 2018 revealed the laboratory utilized the AmediCheck Instant Test Cup test system for Urine Drug Screen (UDS) testing and reporting of Amphetamine (Amph), Barbiturates (Barb), Benzodiazepines (Benzo), Cocaine (COC), MDMA, Methadone (Meth), Methamphetamine (Methamph), Opiates (OPI), Opiate300 (OPI300), Oxycodone (Oxy), Phencyclidine (PCP), Cannabinoids (THC) and Tricyclic Antidepressants (Tricyclic) in patient urine samples. 2. Review of the AmediCheck Instant Test Cup package insert revealed under the "Indications For Use: This test provides only a preliminary result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) or High Performance Liquid Chromatography (HPLC) is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgement should be applied to any drug of abuse test result, particularly when preliminary results are used." 3. Review of the Task 1 and 3 Form submitted to the

	surveyor on February 14, 2018 revealed the laboratory performs the following annual volumes for UDS testing: 146 - Amph, 146 - Barb, 146 - Benzo, 146 - COC, 146 - MDMA, 146 - Meth, 146 - Methamph, 146 - OPI, 146 - OPI300, 146 - Oxy, 146 - PCP, 146 - THC and 146 - Tricyclic. 4. Interview with the Laboratory Director on February 14, 2018 confirmed that patient urine drug screen test results did not include the disclaimer. The Laboratory Director confirmed the UDS test results are not reported as preliminary results and that they do not confirm all UDS results.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to maintain copies of the proficiency testing program attestation statements signed by the analyst and the laboratory director for a minimum of two years for two (2) of twelve (8) Proficiency Test (PT) events reviewed. Findings: 1. Review of American Proficiency Institute (API) PT records from January 1, 2016 through February 14, 2018 revealed the laboratory failed to maintain copies of attestation statements signed by the analyst and the laboratory director for the following two (2) events: a) 2017 Chemistry 2nd Event - the laboratory director failed to sign the attestation. d) 2017 Microbiology 3rd Event - testing personnel failed to sign the attestation. 2. Interview with personnel 2 on February 14, 2018 confirmed the laboratory did not maintain copies of the proficiency testing program attestation statements signed by the analyst and the laboratory director, for the two (2) PT events in 2017 for Hematology.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observation, record review and interview with laboratory personnel the laboratory failed to calibrate laboratory centrifuges at least every 6 months as required by the manufacturer. Findings: 1. Observation by surveyor on February 14, 2018 revealed the laboratory utilized a PSS Select PSS602 Centrifuge for the spinning of patient Chemistry and Endocrinology samples for testing. 2. Review of the PSS Select PSS602 Centrifuge Operators Manual revealed that it is "recommended that your

	centrifuge's rpm be calibrated at least every 6 months." 3. Interview with personnel 2 on February 14, 2018 revealed she was unaware of the manufacturer's requirement to calibrate the centrifuge every 6 months. Personnel 2 did confirm the centrifuge has not been calibrated every 6 months.
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: Based on observation, and interview with laboratory personnel, the laboratory failed to ensure that Access Vitamin B12 Calibrators are not used beyond their expiration dates. Findings: 1. Observation by the surveyors during the tour of the laboratory on February 14, 2018 revealed the following expired items in place for patient testing: Access Vitamin B12 Calibrators - lot number 613098, with an expiration date of 2018-0131. 2. Interview with personnel 2 on February 14, 2017 confirmed by observation the items cited were expired and in place for patient testing.
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: Based on observation, record review and interview with personnel, the laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the Beckman Coulter Access 2 Chemistry Analyzer. Findings: 1. Observation by surveyor on February 14, 2018 revealed the laboratory maintained a Beckman Coulter Access 2 Chemistry Analyzer utilized for the following patient testing: Free Thyroxine (FT4), Thyroid Stimulating Hormone (TSH), Vitamin B12 (B12), Folate, and Vitamin D (VitD). 2. Review of the Laboratory's Policy and Procedure Manual revealed a "Performance Verification Procedure" that was effective November 30, 2012. The Method Validation policy revealed written policies and procedure for: A) Accuracy: is established by comparing results to a definitive or reference method, or may be verified by comparing results to an established comparative method. Use of reference materials (e.g. commercial control material) or other material with known concentrations or activities is suggested is establishing or verifying accuracy. B) Precision: is established by repeat measurement of samples at varying concentrations or activities within-run and between-run over a period of time. C) Reportable Range: the analytic measurement range (AMR) is the range of analyte values that a method can directly measure on the specimen without any dilution or concentration. D) Reference Range: Normal values

	are initially established or verified for each specimen source when appropriate. Literature references or manufacturer package insert may be appropriate, but should be verified based on patient population. Further review of the "Performance Verification Procedure failed to include: a) For Accuracy, Reportable Range and Reference Range: how many samples are needed, who is to perform, and what the acceptability criteria is. b) For Precision: how many samples are needed, who is to perform (to meet operator variance requirement), and what the acceptability criteria is. 3. Review of the Performance Verification Study for the Beckman Coulter Access 2 Chemistry Analyzer revealed: a) Raw data from April 4, 2017 through April 5, 2017 that was signed off by the Beckman Coulter Senior Application Specialist. NOTE: There was no documentation that laboratory personnel participated. b) Simple Precision was calculated, evaluated and signed of by the Laboratory Director NOTE: There was no documentation for within-run, between-run or operator variance. c) Method Comparison: Evaluation of the data was signed of by the Laboratory Director on April 8, 2018. NOTE: The raw data used was from the Beckman Representative d) Tab for Linearity just had a Summary stating the Linearity passed for FT4, TSH, Folate, B12 and VitD. There was no data. The summary was not signed of e) There was no Reference Range Study information. The laboratory failed to maintain all the data to support accuracy, precision, reportable and reference ranges. The data supplied failed to include documentation of laboratory personnel that participated in the performance verification studies. 4. Review of the Task 1 and 3 Form submitted to the surveyors on February 14, 2018 revealed the laboratory performs the following annual volumes: 171 - FT4, 1439 - TSH, 281 - Folate, 289 - B12 and 289 - VitD. 5. Interview with personnel 1 on February 14, 2018 confirmed the laboratory failed to follow laboratory policy for method validation, and confirmed the laboratory failed to maintain documentation to support that laboratory personnel performed the method validation.
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: I. Based on observation, record review and interview with personnel, the laboratory failed to document the weekly maintenance on the Beckman Coulter Access 2 Chemistry Analyzer as required by the manufacturer, for forty two (42) of forty two (42) weeks reviewed. Findings: 1. Observation by surveyor on February 14, 2018 revealed the laboratory maintained a Beckman Coulter Access 2 Chemistry Analyzer utilized for the following patient testing: Free Thyroxine (FT4), Thyroid Stimulating Hormone (TSH), Vitamin B12 (B12), Folate, and Vitamin D (VitD). 2. Review of the Beckman Coulter Access 2 Chemistry Analyzer Log revealed the laboratory is to perform a Weekly System Check that includes: Washed RLU/%CV Substrate RLU/% CV Unwashed RLU/%CV Wash Efficiency Substrate Ratio Substrate: Washed Ratio Techs initials Further review of the Beckman Coulter Access 2 Chemistry Analyzer Log from April 10, 2017 through January 25, 2018 revealed the laboratory failed to document the performance of the Weekly System Check for forty two (42) weeks or 100% of the time. 3. Interview with the Laboratory Director on February 14, 2018 revealed he was unaware the laboratory failed to document the Weekly System Check. Personnel 2 on February 14, 2018 confirmed the laboratory failed to document

	the Weekly System Check. II. Based on observation, record review and interview with personnel, the laboratory failed to document the weekly maintenance on the Vitros 350 Chemistry Analyzer as required by the manufacturer, for seven (7) of forty two (42) weeks reviewed. Findings: 1. Observation by surveyor on February 14, 2018 revealed the laboratory maintained a Vitros 350 Chemistry Analyzer utilized for the following patient testing: Albumin (ALB), Alanine aminotransferase (ALT), Aspartate aminotransferase (AST), Alkaline phosphatase (ALP), Total Bilirubin (TBil), Direct Bilirubin (DBil), Calcium (CA), Chloride (CL), Carbon Dioxide (CO2), Cholesterol (Chol), High Density Lipoprotein Cholesterol (HDL), Creatinine (Creat), Glucose (Glu), Potassium (K), Sodium (NA), Phosphorous (Phos), Total Protein (TP), Triglyceride (Trig), Blood Urea Nitrogen (BUN), and Uric Acid (Uric). 2. Review of the Vitros 350 Chemistry Analyzer Log revealed the laboratory is to perform a Weekly System Check that includes: Clean tray platform and transport arm Clean cup retainer Clean diluent bottles Clean tip locator assembly Clean control unit screen Clean keypad cover Inspect, clean, and/or replace air filter Back up QC/ Conf/ Calibration Data Further review of the Beckman Coulter Access 2 Chemistry Analyzer Log from April 10, 2017 through January 25, 2018 revealed the laboratory failed to document the performance of the weekly maintenance for the following seven (7) weeks: January 30, 2017 - February 3, 2017 February 6, 2017 - February 10, 2017 February 13, 2017 - February 17, 2017 February 20, 2017 - February 24, 2017 February 28, 2017 - March 3, 2017 May 30, 2017 - June 2, 2017 August 28, 2017 - September 1, 2017 3. Interview with the Laboratory Director on February 14, 2018 revealed he was unaware the laboratory failed to document the Weekly System Check. Personnel 2 on February 14, 2018 confirmed the laboratory failed to document the Weekly maintenance.
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 observations, record review and interview with laboratory personnel, the Laboratory Director failed to ensure that verification procedures are performed to determine accuracy, precision, reportable and reference ranges for the Beckman Coulter Access 2 Chemistry Analyzer. Refer to D5421. Interview with personnel 1 on February 14, 2018 confirmed the laboratory failed to follow laboratory policy for method validation, and confirmed the laboratory failed to maintain documentation to support that laboratory personnel performed the method validation.
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 record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required for accurate and reliable results. Findings: 1. The laboratory failed to calibrate laboratory centrifuges at least every 6 months as required by the manufacturerRefer to D5411. 2. The laboratory failed to ensure that Access Vitamin B12 Calibrators are not used beyond their expiration dates. Refer to D5417.
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 review of manufacturer's instructions, instrument maintenance records and interview with laboratory personnel, the Laboratory Director failed to ensure that the laboratory performed the required maintenance to ensure acceptable levels of analytical performance. Findings: 1. The laboratory failed to document the weekly maintenance on the Beckman Coulter Access 2 Chemistry Analyzer as required by the manufacturer, for forty two (42) of forty two (42) weeks reviewed. Refer to D5429 I. 2. The laboratory failed to document the weekly maintenance on the Vitros 350 Chemistry Analyzer as required by the manufacturer, for seven (7) of forty two (42) weeks reviewed. Refer to D5429 II.