Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0931056	03/20/2024
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 Recertification survey was performed at Family Medicine Center Alexandria, CLIA # 19D0931056, on March 20, 2024. Family Medicine Center Alexandria was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1415 CONDITION: Laboratories performing moderate complexity testing; Clinical Consultant
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of CMS-209 (Laboratory Personnel Report), laboratory policy and procedures, and interview with personnel, the laboratory failed to ensure written policies and procedures to assess competency for Clinical Consultant were complete. Findings: 1. Review of the laboratory's CMS-209 form provided to surveyor revealed the laboratory did not have a qualified Clinical Consultant listed on the form. 2. In interview on March 20, 2024 at 11:13 am, the Laboratory Director stated the laboratory is currently filling the position of Clinical Consultant. 3. Review of the laboratory's policy for Clinical Consultant revealed the laboratory did have a policy for duties and responsibilities for the role of Clinical Consultant; however, the policy did not specify a frequency for competency assessment performance. 4. In further interview on March 20, 2024 at 11:13 am, the Laboratory Director confirmed the laboratory did not have a frequency included in the Clinical Consultant policy.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)

	The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of manufacturer's package inserts, laboratory policy and procedures and interview with personnel, the laboratory failed to ensure specimen collection and preparation requirements were maintained as required by the manufacturer. Findings: 1. Observation by surveyor during the laboratory tour on March 20, 2024 at 10:40 am revealed the laboratory utilizes the following analyzers for patient testing: a) Vitros 350 Chemistry analyzer with the following tests: Glucose (Gluc), Blood Urea Nitrogen (BUN), Creatinine (Crea), Sodium (Na), Potassium (K+), Chloride (CL), Carbon Dioxide (CO2), Calcium (Ca), Phosphorus (Phos), Total Protein (TP), Albumin (Alb), Total Bilirubin (TBil), Aspartate aminotransferase (AST), Alanine transaminase (ALT), Alkaline phosphatase (ALP), Direct Bilirubin (DBil), Cholesterol (Chol), Triglyceride (Trig), High Density Lipoprotein (HDL), Uric Acid (UA), Magnesium (Mag) b) Beckman Coulter Access 2 with the following tests: Free Thyroxine (FT4), Thyroid Stimulating Hormone (TSH), Vitamin B12, Folate, Vitamin D 2. Further observation on March 20, 2024 at 10:25 am revealed the laboratory receives specimens from an alternate collection site. 3. In interview on March 20, 2024 at 10:46 am, the Laboratory Director stated the laboratory is currently collecting patient samples at another facility and transporting the uncentrifuged samples to the laboratory within two (2) or more hours. 4. Review of the Beckman Coulter Access 2 chemistry package inserts revealed the manufacturer requirements for the following analytes: a) Vitamin B12: Physically separate serum or plasma from contact with cells as soon as possible b) Thyroid Stimulating Hormone (TSH): Physically separate serum or plasma from contact with cells as soon as possible c) Folate: Physically separate serum or plasma from contact with cells as soon as possible d) Free Thyroxine (FT4): Physically separate serum or plasma from contact with cells as soon as possible e) Vitamin D: Physically separate serum or plasma from contact with cells as soon as possible 5. Review of the Vitros 350 chemistry package inserts revealed the manufacturer requirements for the following analytes: a) Glucose: Centrifuge specimen and remove the serum/plasma from the clot within 30 minutes after collecting specimen to avoid metabolism of glucose by the cells b) Potassium: Centrifuge specimens and remove the serum or plasma from the cellular material within 2 hours of collection c) Magnesium: Centrifuge specimens and remove the serum or plasma from the cellular material as soon as possible after collection 6. In interview on March 20, 2024 at 10:46 am, the Laboratory Director confirmed the laboratory did not send the patient samples with the current specimen handling and preparation as required by the manufacturer.
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 maintenance logs and interview with personnel, the laboratory failed to perform weekly maintenance procedures per manufacturer's requirements for two (2) of two (2) chemistry analyzers in 2023. Findings: 1. Observation by surveyor during the laboratory tour on March 20, 2024 at 10:40 am revealed the laboratory utilizes the following two (2) chemistry analyzers for patient testing: a) Beckman Coulter Access 2 b) Vitros 350 2. Review of the maintenance logs for the Beckman Coulter Access 2 chemistry analyzer revealed the laboratory performs the following weekly maintenance: a) Clean Instrument Exterior b) Inspect Liquid Waste Bottle c) Check Wast Filter Bottle d) Inspect/Clean Primary Probe e) Replace/Clean Aspirate Probes f) Run Daily Maintenance g) Run System Check 3. Review of maintenance logs for the Vitros 350 chemistry analyzer revealed the laboratory performs the following weekly maintenance: a) Clean tray platform and transport arm b) Clean cup retainer c) Clean diluent bottles d) Clean tip locater assembly e) Clean control unit screen f) Clean keypad cover g) Inspect, clean, and/or replace air filter h) Back up QC/Config/Calibration Data 4. Further review of the 2023 maintenance logs for the Beckman Coulter Access 2 and the Vitros 350 chemistry analyzers revealed the weekly procedures were not performed for the following weeks: a) Beckman Coulter Access 2: maintenance not performed for week of October 31, 2023 through November 6, 2023 b) Vitros 350: maintenance not performed for week of November 30, 2023 through December 6, 2023 5. In interview on March 20, 2024 at 3:10 pm, the Laboratory Director confirmed the identified weekly maintenance was not performed as required by the manufacturer.
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 ensure specimen collection and preparation requirements were maintained as required by the manufacturer. Refer to D5311. 2. The laboratory failed to perform weekly maintenance procedures per manufacturer's requirements for two (2) of two (2) chemistry analyzers in 2023. Refer to D5429.
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) 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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate

	consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by: Based on review of CMS-209 (Laboratory Personnel Report), laboratory policy and procedures and interview with personnel, the Laboratory Director failed to ensure the laboratory employed a Clinical Consultant to consult with and render opinions to the laboratory's clients. Refer to D6057.
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 laboratory policy and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Findings: 1. The laboratory failed to ensure written policies and procedures to assess competency for Clinical Consultant were complete. Refer to D5209.
D6056	CLINICAL CONSULTANT CFR(s): 493.1415 The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part. This CONDITION is not met as evidenced by: Based on review of personnel records and interview with personnel, the laboratory failed to ensure the position of Clinical Consultant was employed based on requirements for moderate complexity testing. Refer to D6057.
D6057	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1417 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493. 1405(b)(1), (2), or (3)(i); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or

	podiatry in the State in which the laboratory is located. This STANDARD is not met as evidenced by: Based on review of the Laboratory Personnel Report (CMS 209) and personnel records as well as interview with personnel, the laboratory failed to ensure the laboratory employed a qualified Clinical Consultant as required. Findings: 1. Review of the Laboratory Personnel Report (CMS 209) and personnel records revealed the laboratory does not have personnel serving in the position of Clinical Consultant. 2. In interview on March 20, 2024 at 11:13 am, the Laboratory Director stated the previous Clinical Consultant left the position in December 2023. The Laboratory Director confirmed the laboratory does not have personnel serving as Clinical Consultant.