Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D2074553	12/07/2018
Name of Provider or Supplier	**Street Address, City, State**	
Kc Bariatric	21975 W 83rd St, Lenexa, KS	

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
D3003	FACILITIES CFR(s): 493.1101(a)(2) The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized. This STANDARD is not met as evidenced by: Based on observation and interview with the laboratory director, the laboratory failed to minimize contamination of reagents, equipment and patient samples. Findings: 1. Observation of the laboratory area revealed approximately 495 cases of patient vitamins stored near patient samples, reagents, and laboratory equipment. 2. Interview with the laboratory director on December 7, 2018 at 11:30 AM confirmed the owner stores the vitamins for patient use within the laboratory testing area.
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 review procedures and interview with the laboratory director, the laboratory failed to include a specimen acceptability, step by step procedure for the chemistry and hematology analyzer (refer to 05403); failed to follow the manufacturer's

	guidelines for reagent and specimen stability (refer to 05411); failed to store reagents appropriately (refer to 05412).
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the procedure revealed and interview with the laboratory director on December 7, 2018 at 11:30 AM confirmed, the laboratory failed to include a specimen acceptability and rejection policy and a step by step procedure for complete blood cell counts performed on the ACT T diff 2 and chemistry testing on the AU 480 analyzer.
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 review of the specimen storage and stability policy, manufacturer's reagent inserts for the AU 480 chemistry analyzer, observation of reagents located in the refrigerator and specimens located in the freezer, and interview with Beckman Coulter technical support and the laboratory director, the laboratory failed to following reagent stability instructions for magnesium (Mg), bicarbonate (C02) and creatinine (Creat) and failed to following specimen storage and stability for Mg, C02, sodium (Na), potassium (K), chloride (Cl), albumin (Alb), HDL, iron (Fe), total protein (TP). Findings: 1. Review of the specimen storage and stability policy revealed "Chemistry specimens can be stored at RT during the day of collection or poured off and frozen until day of testing. Refrigerated specimens are stored at 4 degrees Celsius (C) and chemistry specimens are frozen at -20 degrees C. 2. Review of the Beckman Coulter

	AU 480 manufacturer's reagent inserts for Mg, C02, Creat showed "opened reagent is stable for 7 days when stored in the refrigerated compartment of the analyzer". 3. Review of the Beckman Coulter AU 480 manufacturer's specimen stability inserts for Na, K, Cl, Mg, Fe revealed "analytes are stable up to one week when stored 2-8 degrees Celsius (C)". Review of the Beckman Coulter AU 480 manufacturer's specimen stability inserts for C02 revealed "bicarbonate is stable for several hours when stored at 2-8 degrees C". Review of the specimen stability insert for TR and Alb revealed "total protein is stable in serum for one week at room temperature and for one month refrigerated (2- 8 degrees C)". Review of the insert for HDL revealed "serum should not remain at 15 -30 degrees C longer that 14 hours. If analysis is not completed within 14 hours serum may be stored at 2-8 degrees C for up to 1 week. If specimens need to be stored for more than 1 week they may be preserved at less than -70 degrees C for up to 3 months. Samples should only be frozen once". 4. Observation of the AU 480 reagents stored in the refrigerator showed one bottle of Mg reagent Lot #2568, one bottle C02 reagent, and one bottle Creat lot # 2570 all opened with no date or initials. 5. Observation of the freezer revealed specimens stored at a frozen state until batch testing of once a week. 6. Phone interview with Beckman Coulter technical support on December 7, 2018 at 9:30 AM confirmed "the laboratory must follow the reagent inserts and are not allowed to pour off the reagents and store the bottles in the refrigerator to increase storage life". Phone interview with technical support confirmed the laboratory must follow the inserts in regards to specimen storage and stability. 7. Interview with the laboratory director on December 7, 2018 at 9:45 AM confirmed the "laboratory pours off from the original reagent container into a separate container on the analyzer. The original reagent container is kept in the refrigerator until the reagent is used up. The reagent once opened is utilized past the 7 day stability date". Interview with the laboratory director confirmed the "specimens are spun down, poured off and put into the freezer until batch testing that occurs once a week."
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the manufacturer's inserts and interview with the laboratory director, the laboratory failed to monitor and document the humidity of the laboratory for proper operation of the Act T diff 2 hematology analyzer. Findings: 1. Review of the manufacturer' s product insert for performance specifications revealed to operate the analyzer in a humidity no higher than 85 percent without condensation. 2. Review of the room temperature re documentation logs showed the laboratory failed to monitor and document humidity. 3. Interview with the laboratory director on December 7, 2018 at 11:30 AM confirmed the laboratory failed to monitor and document the humidity in the laboratory .
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

	CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of reagents stored in the refrigerator and interview with the laboratory director, the laboratory failed to document the open and expiration date. Findings: 1. Observation of one bottle of magnesium reagent (lot #2568), one bottle carbon dioxide, one bottle creatinine (lot #2570), one bottle T4 (lot# 72940019) showed no open or expiration dates noted on the bottles. 2. Interview with the laboratory director on December 7, 2018 at 11:30 AM confirmed the laboratory failed to include an open and expiration date on the reagents in use on the AU 480 chemistry analyzer.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of 2017 calibration verification documentation for the AU 480 chemistry analyzer for the analytes of sodium, potassium, chloride, bicarbonate , alkaline phosphatase, AST, ALT, total bilirubin, iron, uric acid, magnesium , total protein, calcium, albumin, phosphorus, glucose, creatinine, blood urea nitrogen, cholesterol, high density lipoprotein, triglycerides, and interview with the laboratory director, the laboratory failed to perform at least a three point calibration every six months. Findings: 1. Review of 2017 calibration documentation for the AU 480 chemistry analyzer revealed the laboratory failed to perform at least a 3 point calibration, including at least a minimal, mid-point, and maximum value every 6

	months for the analytes: sodium, potassium, chloride, bicarbonate, alkaline phosphatase, AST, ALT, total bilirubin, iron, uric acid, magnesium, total protein, calcium, albumin, phosphorus, glucose, creatinine, blood urea nitrogen, cholesterol, high density lipoprotein and triglycerides. 2. Interview with the laboratory director on December 2, 2018 at 11:30AM confirmed the laboratory failed to perform at least a 3-point calibration verification on the AU 480.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of training documentation for 3 of 3 moderate complexity testing personnel and interview with the laboratory director on December 7, 2018 at 11:30 AM, the laboratory director failed to ensure initial training was completed prior to patient testing.
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 the hematology procedure manual for complete blood cell counts (CBC) and chemistry testing on the AU 480 and Access 2 and interview with the laboratory director on December 7, 2018 at 11:30 AM, the laboratory director failed to ensure that an approved procedure manual is available to all personnel.