Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D0537398	06/27/2019
Name of Provider or Supplier	**Street Address, City, State**	
C-B Laboratory Inc	313 W Country Club #8, Roswell, NM	

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	The following deficiencies were cited as the result of a recertification survey completed on 06/27/29 for 42 CFR part 493 Laboratory Requirements.
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 of laboratory supplies and manufacturer's labeling, the laboratory failed to ensure the reagents and standards were not expired. Findings are: A. During observation of laboratory supplies on 06/25/19 at 2:36 pm, an expired bottle of 10% KOH solution was found next to the microscope. MCC 10% KOH, dated 09/26/16, lot 704256 expiration date April 2018. B. During observation of laboratory supplies on 6/26/19 at 3:59 pm, the McFarland's Standards used in antimicrobial testing were were expired. C. Remel McFarland Equivalence Turbidity Standard Lot 954654 expiration date 02/16/2018.
D5809	TEST REPORT CFR(s): 493.1291(e) The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, as applicable, the performance specifications established or verified as specified in 493.1253. In addition, information that may affect the interpretation of test results, for example test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results.

	This STANDARD is not met as evidenced by: Based on the review of FDA (Food and Drug Administration) safety notices, manufacturer's bulletin and interview with the Laboratory Owner, the laboratory failed to inform its clients regarding potential inaccuracies for tests affected by high biotin (Vitamin B7) levels. Findings are: A. Review of the FDA Safety Notice date 11 /28/17 indicated "Biotin in patient samples can cause falsely high or falsely low results, depending on the test." B. Review of an undated Roche bulletin confirmed that the laboratory had received notice of the potential problem the use of biotin supplements at >10,000 micrograms per day could have on tests performed using the Roche C411 chemistry analyzer. C. During interview on 06/25/19 at 10:45 am, the Laboratory Owner stated that the laboratory had not provided this information to its clients either in official notifications or as part of the patient report.
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 personnel files, CMS Personnel Report Form 209, laboratory policy and interview with laboratory staff, the Laboratory Director failed to ensure policies were followed for documentation of training for 1 (TP #4) of 4 (TP #1 - #4) moderate complexity testing personnel. Findings are: A. Review of the CMS Personnel Report Form signed by the Laboratory Director on 06/24/19 indicated that TP #4 performed moderate complexity testing. B. Review of the personnel file for TP #4 revealed no documentation of training other than the date of training for collections on 07/26/18. The various training forms, including for the Ruby hematology analyzer, were in the file but not checked or dated. C. Review of the "Training / Competency Protocol" (undated) found in each testing person's file indicated the following policy: "When an employee is trained on a procedure, protocol or instrument a training log will be filled out and placed in the employees file. The master training/competency checklist will also be marked with the date of the training." D. During interview on 06 /24/19 at 11:30 am the Laboratory Owner (TP #1) stated that she "knows there are a lot of blanks" in the personnel files. E. During interview on 06/26/19 at 09:36 am, TP #4 stated that TP #2 did provide training in the laboratory, including on the Ruby hematology analyzer. He further stated that TP #2 was going to update his training forms and he did not have any copies of training documents.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least

	semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of personnel files, CMS Personnel Report Form 209, laboratory policy and interview with laboratory staff, the Technical Consultant failed to ensure written policies were created and followed for monitoring competency for 1 (TP #4) of 4 (TP #1 - #4) moderate complexity testing personnel. Findings are: A. Review of the CMS Personnel Report Form signed by the Laboratory Director on 06/24/19 indicated that TP #4 performed moderate complexity testing. B. Review of the personnel file for TP #4 revealed no documentation of a competency evaluation since TP #4 was hired. Training checklists indicate he was working in the laboratory July of 2018. C. During interview on 6/26/19 at 5:09 pm, the Laboratory Owner (TP #1) stated TP #4 started work in the laboratory on 07/09/18. D. During the entrance interview on 06/24/19 at 11:30 am the Laboratory Owner stated that she "knows there are a lot of blanks" in the personnel files. E. Review of the laboratory's undated competency policy indicated the "Competency checks will be performed after training on an instrument or test procedure and again on a yearly basis. The Medical Director, who will sign the employee off for each instrument or test procedure, will do these checks."
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must 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 the review of personnel files, laboratory policy and interview with the Laboratory Owner, the Laboratory Director failed to ensure that policies were followed for competency evaluations for 3 of 3 high complexity testing personnel. Findings are: A. Review of personnel files revealed no documentation of competencies since 2016 for 3 (TP #1 -TP #3) of 3 high complexity testing personnel. B. During interview on 06/24/19 at 11:30 am the Laboratory Owner (TP #1) stated that she "knows there are a lot of blanks" in the personnel files. She also stated that TP #3 did not work in the laboratory except as needed. C. Review of the laboratory's undated competency policy indicated the "Competency checks will be performed after training on an instrument or test procedure and again on a yearly basis. The Medical Director, who will sign the employee off for each instrument or test procedure, will do these checks."