Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D0536885	08/27/2018
Name of Provider or Supplier	**Street Address, City, State**	
Colfax General Laboratory	615 Prospect Ave, Springer, 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 deficiency was cited as the result of a recertification survey on 08/27/2018 for 42 CFR part 493 Laboratory Requirements.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of chemistry quality control records and interview with the laboratory supervisor, the laboratory failed to have an effective quality control program to monitor quality control over time. This deficient practice could likely result in a failure to identify quality control and instrument failures. Findings are: A. Review of the laboratory's chemistry quality control records revealed the laboratory did not have a system to monitor quality control results using a fixed acceptable quality control range and mean. 1. The laboratory manually entered the data points into an online statistics program to obtain the mean and standard deviation (SD) for that month. 2. There was no documentation indicating the technical consultant assessed the quality control data using the mean and SD for the entire lot of controls, not just the current month. B. Review of Alkaline Phospatase quality control data revealed a shift upward in values over 5 months. Precinorm U Plus (PPU) Lot

	20306004 expiration date 06/2019. The target mean (from the instrument printout since the lot was put into use) was 207 U/L and the SD was 13.32 for a 2 SD range 180.36 - 233.64. 1. April 2018 Monthly calculated PPU mean = 199.21 SD = 3.78 2 SD range 191.65 - 206.77 2. May 2018 Monthly calculated PPU mean = 201.55 SD = 7.88 2 SD rage 185.79 - 217.31 3. June 2018 Monthly calculated PPU mean = 203.06 SD = 7.35. 2 SD range 188.36 - 217.76 4. The actual mean (from the instrument printout for July 2018) was 207 U/L and the SD was 10.0. 2 SD range 187 - 227. 5. The actual mean (from the instrument printout for August 9 - August 27, 2018) was 210 U/L and the SD was 9.0. 2 SD range 192 - 230. C. Review of the laboratory's established quality control ranges indicated the laboratory had changed the Alkaline Phosphatase and other analyte ranges based on the monthly data. 1. The laboratory's quality control ranges were revised on 07/23/2018 and 08/08/2018 for the current lot of controls. The previous lot, 18634501, expired on 02/27/2018. a. On 7/23/2018, the mean for Alkaline Phosphatase was 201 U/L and the SD was 12 for an acceptable 2 SD range of 177 - 225. b. On 8/08/2018, the mean was changed to 207 and the SD remained 12 for an acceptable 2 SD range of 183 - 231. D. During interview on 08/27 /18 at 4:15 pm, the laboratory supervisor confirmed the following: 1. The laboratory did not establish the new chemistry quality control ranges prior to putting the new lots of controls into use. 2. The laboratory entered the monthly quality control data into an online statistics calculator and printed the results for review by the technical consultant. 3. The technical consultant did not review the quality control files from the COBAS C 111 chemistry analyzer. 4. The COBAS C 111 maintained only 2 months of quality control data onboard the analyzer.