Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D0880233	12/01/2020
Name of Provider or Supplier	**Street Address, City, State**	
Centers For Disease Control & Prevention	3156 Rampart Rd, Fort Collins, CO	

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
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of 2019 and 2020 instrument comparison documentation and interview with the Technical Supervisor (TS) #1, the laboratory failed to perform instrument comparisons for the BioRad CFX96 PCR detection system used for Colorado tick fever molecular testing two times a year. Findings: 1. Review of the BioRad CFX96 PCR detection system records showed the laboratory failed to perform instrument comparisons for the two BioRad CFX96 PCR detection system, analyzers #242 and #248 two times a year for 2019 and 2020. 2. Interview with the TS #1 on December 1, 2020 at 1:00 PM confirmed, the laboratory failed to perform instrument comparisons for the two BioRad CFX96 PCR detection system two times a year for 2019 and to date 2020.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must 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 "Reagent Procedure Manual" and interview with the Technical

	Supervisor (TS) #2, the laboratory failed to ensure the Laboratory Director (LD) approved the procedure manual for personnel responsible for any aspect of the testing process. Findings: 1. Review of the "Reagent Procedure Manual" showed a lack of approval by the LD. 2. Interview with the TS #2 on December 1, 2020 at 1:30 PM confirmed the procedure manual available to personnel was not approved by the LD.