Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0644240	01/11/2018
Name of Provider or Supplier	**Street Address, City, State**	
Shasta County Public Health Lab	2650 Breslauer Way, Redding, CA	

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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on request, and the lack of documentation for performance specifications of two (2) Applied Biosystems 7500 instruments Serial Number (SN) # 275030181 and SN # 275030936 acquired in 2016, random patient test results, and interview with the technical consultant, it was determined that the laboratory failed to perform verification of performance specification studies for the above instruments. The findings included: a. The laboratory lacks the documentation for verification performance specifications for the two (2) Applied Biosystems 7500. b. For two (2) out of eight (8) random patient test results reviewed covering period from 1/4/2016 to 11/27/2017, the laboratory analyzed and reported two (2) patients; one had ordered for Bordetella pertussis test and one had ordered for Influenza test which results may be affected by the lack of instrument's performance specification studies. c. The technical consultant affirmed (1/11/2018, 1230PM), that the laboratory has no documentation to show for its instruments verification of performance.
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 request, and the lack of documentation for comparison of two (2) Applied Biosystems 7500 instruments Serial Number (SN) # 275030181 and SN # 275030936 acquired in 2016, review of the laboratory's policy and procedure manual, random patient test results, and interview with the technical consultant, it was determined that the laboratory failed to perform comparison studies for the above instruments. The findings included: a. Review of the laboratory's policy and procedure stated that: "Chapter 11. Comparison of Test Results. A. Comparison of Test Results. Conduct parallel studies to compare test methods or instruments." b. For two (2) out of eight (8) random patient test results reviewed covering period from 1/4/2016 to 11/27/2017, the laboratory analyzed and reported two (2) patients; one had ordered for Bordetella pertussis test and one had ordered for Influenza test which results may be affected by the lack of instrument's comparison studies. c. The technical consultant affirmed (1/11 /2018, 1230PM), that the laboratory has no documentation to show for its instruments comparison studies.