Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0644064	05/03/2022
Name of Provider or Supplier	**Street Address, City, State**	
Sonoma County Public Health Laboratory	3313 Chanate Rd, Santa Rosa, 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
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 the laboratory's reagent materials used for decontamination of surface areas and other reagents used in the laboratory and interview with the laboratory director (LD); it was determined that the laboratory failed to label various reagents to indicate the reagent's name, opening, preparation, and expiration dates when such reagents are used in the laboratory. The findings included: 1. Based on the surveyor's observation during the laboratory tour on May 3, 2022, at approximately 1: 00 pm.; no opening, preparation, or expiration date labels were used or documented for various reagents used throughout the laboratory (1:10 Sodium hypochlorite and sterile water). 2. The laboratory's LD affirmed in an interview conducted May 3, 2022, at approximately 1:15 p.m. that the reagents mentioned in statement 1 were not labeled with the name, opening, preparation, and expiration dates or documented. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed approximately 105,103 test samples.
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 the incomplete laboratory's verification of performance characteristics for high complexity testing for Lyme Disease by ELISA, interview with the laboratory director (LD), and six (6) randomly selected patient test records reviewed from 1/8/2020 to 1/4/2022; the laboratory failed to demonstrate that it established performance specifications comparable to those established by the manufacturer. The findings included: 1. The laboratory had only partial documentation to show for performance specifications, no date or signature of approval by the LD prior to reporting patient test results. The laboratory must be able to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics and those to be approved by the LD before starting testing patients' samples: (A) Accuracy (B) Precision (C) Reportable range of test results for the test system (D) Sensitivity and (E) Specificity. 2. The laboratory was unable to provide for review additional documents using patient samples to establish the performance specifications stated in 1. 3. The LD affirmed at the time of the survey on 05/03/2022 at approximately 11:30 a.m. that no additional documents could be retrieved to show that all the Lyme Disease test by ELISA method performance specifications were performed prior to reporting patient test results when the laboratory went live testing and reporting Lyme Disease diagnostic tests. 4. Based on the estimated annual tests volumes reported on 5/03/2022; the laboratory performed and reported approximately 227 Lyme Disease test results by the ELISA method. The precision and reliability of the reported results could not be assured.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on the laboratory's procedure manual, lack of documentation, observation, and interview with the laboratory director and testing personnel (TP); it was determined that the laboratory failed to perform and document maintenance and calibration as defined by the manufacturer and with at least the frequency specified by the manufacturer for the laboratory's small equipment such as vortexes, centrifuges, and timers. The findings included: 1. The laboratory's standard operating procedure (SOP) indicated that annual maintenance and calibration be performed according to manufacturer's requirements on small equipment: vortexes, centrifuges, and timers. 2. The LD and TP confirmed on May 3, 2022, at approximately 1:00 p.m. that the laboratory failed to follow the SOP for maintenance and calibration of small equipment used in the laboratory. 3. According to the annual test volume declared by the laboratory on 5/3/2022 the laboratory performs approximately 105,103 tests annually.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on review of the laboratory's incomplete validation and verification of performance specifications for a new test, lack of labelling of reagents, lack of preventive maintenance of small equipment, and interview with the laboratory director and testing personnel on May 3, 2022; it was determined that the laboratory director failed to ensure that several aspects of the preanalytic, analytic, and posanalytic phases of laboratory testing were monitored. See D5415, D5421, and D5429.