Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0644064	03/15/2019
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
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 the laboratory test list (Laboratory Testing Declaration, 3/11/19) and patients laboratory reports for Bordetella pertussis (Pertussis) including Culture and Molecular diagnostics methods, the lack of laboratory documents, and interview with Testing person-5 (Technical Supervisor) it was determined that the laboratory failed to have a system that twice each year compared the relationship of the different methodologies for Pertussis. a. Ten of 10 laboratory reports selected at random from 2017 and 2018 included Pertussis results by both Culture and PCR. b. The laboratory was unable to provide for review a policy and documents comparing Pertussis Culture and PCR methods and results at least twice a year. c. Testing person-5 (Technical Supervisor) affirmed (3/12/19 at 5pm) the aforementioned lack of documents; and thus the laboratory's failure to compare and document evaluations of the different methods of testing for Pertussis. d. The reliability and quality of comparisons between Culture and PCR could not be assured in the absence of a policy and procedure to collect and document the evaluation of actual data twice each year. e. Based on the stated test volumes (Laboratory Testing Declaration), the laboratory annually reported 67 Culture results and 98 PCR results. Examples are as follows: Date Lab # ---------- 2/03/17 17B0016 3/25/17 17B0048 4/20/17 17B0065 8/11/17 17B0142 9/06/17 17B0152 2/23/18 18B0031 3/15/18 18B0044 5/21/18 18B0065 5/21/18 18B0066 5/31/18 18B0073

D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on the serious nature of the deficiency cited (D6078), the Condition of laboratory director, high complexity testing was not met.
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification. This STANDARD is not met as evidenced by: Based on review of personnel records, the lack of records documenting training at a public health microbiology laboratory (PHL) and work experience as a PHM, and interview with Testing person-5, the laboratory director did not meet the State's qualifications to manage and direct laboratory personnel and performance of high

	complexity tests at a public health microbiology laboratory. Findings included: a. Testing person-5 affirmed (3/12/19) not having work experience as a PHM nor PHM supervisory experience prior to 2016. b. The Section Chief for State Personnel Licensing evaluated the records and documents submitted by Testing person-5 and determined that the information needed to verify training at a PHL and determine PHM work experience was not provided; and thus was not acceptable. The Section Chief communicated this by email to Testing person-5 on May 2, 2019. c. Records provided by Testing person-5 failed to include at least 4 years of work experience as a PHM, with 2 years of supervisory responsibilities; as required for State qualifications.