Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0668137	08/29/2023
Name of Provider or Supplier	**Street Address, City, State**	
Ventura County Health Department Lab	2240 E Gonzales Rd Ste 160, Oxnard, 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
D2047	PARASITOLOGY CFR(s): 493.829(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of the College of American Pathologists (CAP) proficiency testing (PT) records and interview with the laboratory director (LD) and technical supervisor (TS) for the second event of 2022 (Q2-2022); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Parasitology identification of parasites. The findings included: 1. CAP reported an unsatisfactory score of 78 % for the identification of parasitology parasites. 2. The LD and TS affirmed on August 29, 2023, at approximately 11:00 a.m. that the laboratory received the above unsatisfactory proficiency testing score. 3. Based on the laboratory's annual declaration the laboratory analyzed and reported 897 parasitology test result for which the result cannot be assured.
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 the surveyor's observation of the laboratory's reagent materials used in the

	laboratory and interview with the laboratory director (LD) and technical supervisor (TS); 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 of the Bacteriology section on August 29, 2023, at approximately 1:00 pm.; no opening, preparation, or expiration date labels were used or documented for various reagents used throughout the laboratory. 2. The laboratory's LD and TS affirmed in an interview conducted on August 29, 2023, at approximately 1:15 p.m. that various reagents used throughout the Bacteriology section were not labeled with the name, opening, preparation, and expiration dates or documented in a preparation log. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed approximately 72,952 test samples.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on the surveyors' observation, examination of laboratory reagents, and interview with the laboratory director (LD) and technical supervisor (TS); it was determined that the laboratory failed to not store and use reagents when they have exceeded their expiration date. The findings included: 1. On the day of inspection, August 29, 2023, at approximately 1:00 p.m. the surveyor found while touring the Bacteriology laboratory section the following reagent used beyond its expiration date: diagnostic antibiotic disks, Kovac's reagent, Zinc dust, and others. 2. The LD and TS affirmed on August 29, 2023, at approximately 1:15 p.m. storing in the refrigerator the reagents listed on 1 beyond its expiration date. 3. Based on the laboratory's submitted testing declaration volume, the laboratory tests and reports approximately28, 720 Bacteriology tests samples annually.
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 review of the laboratory's procedure manual, lack of documentation, the surveyor's observation, and interview with the laboratory director (LD)and the technical supervisor (TS); 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 thermometers and timers. The findings included: 1. The laboratory's standard operating procedure (SOP) indicated that maintenance and calibration be performed according to manufacturer's requirements on all equipment used in the laboratory. 2. The LD and TS confirmed on August 29, 2023, at approximately 1:10 p.m. that the laboratory

	failed to follow the manufacturer's instructions on preventive maintenance and calibration of small equipment such as timers and thermometers used in the laboratory. 3. According to the test volume declared by the laboratory on 8/29/2023 the laboratory performs approximately 72,952 diagnostic 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 records for policies and procedures, patients' test results records, proficiency testing reports, direct observation by the surveyors during the lab tour, and interviews with the laboratory director and technical supervisor on August 29, 2023; it was determined that the laboratory director failed to ensure that several aspects of the preanalytic, analytic, and postanalytic phases of laboratory testing were monitored. See D2047, D5415, D5417, and D5429.