Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0665059	01/16/2018
Name of Provider or Supplier	**Street Address, City, State**	
San Bernardino County Pub Hth Lab	150 E Holt Blvd, Ontario, 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 laboratory's proficiency testing results reports, and interview with the laboratory staff, it was determined that the laboratory failed to attain an overall testing event score of at least 80 percent is unsatisfactory performance. The findings included: a. The laboratory performed parasitology and enrolled its proficiency testing with CAP (College of American Pathologist) PT program to verify the accuracy of its testing performance annually. b. The laboratory attained a score of 60 % for parasitology in the 2nd 2017 PT event, which was unsatisfactory performance. c. The laboratory performed parasitology in approximately one patient sample monthly. d. The laboratory staff affirmed (01/16/2018 @12:35 pm) that the laboratory attained a score of 60 % for parasitology in the 2nd 2017 PT event, which was unsatisfactory performance.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory written policies and procedures, and interview with the laboratory staff, it was determined that the laboratory procedures and changes in procedures must be approved, signed, and dated by the current laboratory director

	before use. The findings included: a. No evidences at the time of the survey (01/16 /2018) of the written policies and procedures or changes in P & P were approved, signed, and dated by the current laboratory director before use.
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 supplies and control materials, and interview with the laboratory staff, it was determined that the laboratory failed to label thematerial currently opened and used to indicate the preparation and expiration dates. The findings included: a. The laboratory used Beckman flow cytometer, model Aquios el to report CD4, CD8 etc. b. The control materials currently used were not labeled to indicate the expiration dates. c. The laboratory staff affirmed (01/16/2018 @ 13:10 pm) that the controls were not labeled.
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 observation and interview withe laboratory staff, it was determined that the laboratory failed to discard the reagent when they have exceeded their expiration date, have deteriorated, or are of substandard quality. The findings included: a. There was a bottle of reagent labeled as Dobell O'Connor iodine for concentration method of Ova and Parasite testing. b. The expiration date for this reagent was dated 12/29/2015, then cross out and redated to 12/2016. c. The laboratory staff discarded the reagent right at my presence.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on observation and review of the laboratory's temperature charts and interview with the laboratory staff, it was determined that the laboratory failed to detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. The findings included: a. The laboratory use refrigerators and freezers to maintain and ensure the quality of any laboratory supplies, samples, and/or reagents. b. There were no temperature recorded for the dates on the weekends or holidays where no personnel come to the laboratory. c. One two-door refrigerator, Fisher Isotemp Plus, located in the area where culture media and samples kept had built in temperature monitor. d. The screen for the temperature condition showed and indicated "Pout", which translated to be "power out" at some time, yet not been noticed and investigated. e. The built-in temperature indicated 3.6 oC noted at the time of the survey (1/16/2018 @ 10:45 am) while the bottled thermometer indicated at 5 oC. f. There are two monitor systems for the temperature and showed inconsistent temperature reading. g. The laboratory failed to investigate and document all control procedures performed.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (E) The laboratory director must-- (E)(1) 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 observation, review of the laboratory records, and interview with the laboratory staff, it was determined that the laboratory director failed to be responsible for the overall operation, including, but are not limited to 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. The findings included: See D-5407, D-5415, D-5417, and D-5441