Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0665059	02/06/2024
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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on the lack of laboratory written policies and procedures for KOH and interviews with the laboratory director (LD), technical supervisor (TS), and testing personnel (TP); it was determined that the laboratory failed to have available and follow written procedures for KOH-mycology testing. The findings included: 1. On the day of the survey on February 6, 2024, at approximately 3:30 p.m., the laboratory failed to provide written policies and procedures for KOH-mycology testing. 2. For one (1) out of five (5) randomly selected patient test results for microbiology tests performed in the lab, no KOH standard operating procedure (SOP) was available at the time of survey. 3. The LD and TS confirmed on 02/06/2024 at approximately 3:30 p.m. that the laboratory did not have written policies and procedures available for performance of KOH mycology testing.
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 surveyors' observation during the laboratory tour and interview with the laboratory director (LD) and technical supervisor (TS), the laboratory failed to label reagents and stains throughout the laboratory. The findings included: 1. Based on the surveyor's observation during the laboratory's tour on February 6, 2024, at approximately 3:00 p.m..; no opening, preparation, or expiration date labels were used or documented for the reagents and stains (ex: water, alcohol, gram and TB stains). 2. The LD and TS affirmed in an interview conducted 2/06/2024, at approximately 3:30 p.m. that the reagents mentioned in statement 1 were not labeled with the 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 31,801 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), technical supervisor (TS) and testing personnel (TP); 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, February 6, 2024, at approximately 3:00 p.m. the surveyors found while touring the laboratory sections the following reagent used beyond its expiration date: immersion oil, Cavicide, DI water, and ethanol. 2. The LD, TS, and TP affirmed on February 6, 2024, at approximately 3:15 p.m. storing throughout the laboratory the reagents listed on statement 1 is beyond its expiration date. 3. Based on the laboratory's submitted testing declaration volume signed and dated by the LD, the laboratory tests and reports approximately 31,801 test 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 the laboratory's policies and procedures, lack of documentation, and interview with the laboratory director (LD), technical supervisor (TS) and testing personnel (TP), it was determined that the laboratory failed to perform and document preventive maintenance and calibration for the timers as defined by the manufacturer and with at least the frequency specified by the manufacturer for the laboratory equipment. The findings included: 1. The laboratory's policies and procedures indicated that annual maintenance and calibration according to manufacturer's requirements be performed on all equipment used in the laboratory (ex: timers). 2. The LD, TS and TP confirmed on February 6, 2024, at approximately 3:00 p.m. that

	the laboratory failed to follow policies and procedures for maintenance and calibration of the timers used in throughout the laboratory, indicated by the lack of preventive maintenance documentation. 3. According to the annual test volume declared by the laboratory LD, the laboratory performs approximately 31,801 tests annually.
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 the surveyors' review of the laboratory quality control (QC) records, randomly chosen patients' test results, lack of QC documentation, and interviews with the laboratory director (LD), technical supervisor (TS) and testing personnel (TP); it was determined that the laboratory failed to establish and perform quality control procedures that monitor the accuracy and precision of the complete analytic process including the number, the type, and the correction and documentation of those QC performed for KOH mycology testing. The findings included: 1. On the day of the survey last February 6, 2024, at approximately 3:30 p.m., the surveyors observed that QC was not performed for KOH tests. In addition, patient samples were examined, and results were reported despite the lack of QC performed. 2. The LD, TS, and TP confirmed on February 6, 2024, that the laboratory lacked an established policy and procedure for KOH QC. 3. According to the annual test volume declared and signed by the laboratory LD on February 6, 2024, the laboratory performs approximately 100 mycology tests annually including KOH preparation.
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 the surveyors' observation, review of laboratory records, lack of standard operating procedures, quality control documentation, preventive maintenance, labelling and expiration date of reagents and interviews 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 and analytic phases of testing. The findings included: See D5401, D5415, D5417, D5429, and D5441.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on the lack of written procedures and records for positive and negative quality control each day of KOH testing, the technical supervisor is herein cited for deficient practice in their responsibility to always provide scientific oversight and establish quality control programs in accordance with State and CLIA requirements. See D5441.