Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0643851	12/04/2020
Name of Provider or Supplier	**Street Address, City, State**	
Microbial Diseases Laboratory (Mdl)	850 Marina Bay Pkwy Ste E164, Richmond, 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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on laboratory personnel interviews and Foodborne & Waterborne Diseases Section policies and procedures record review on December 2, 2020, the laboratory failed to establish written policies and procedures for specimen labeling. Findings included: a. In the Foodborne & Waterborne Diseases Section, the laboratory routinely accepted patient specimens for bacteriology testing. b. According to laboratory personnel, at a minimum, the patient's name and unique identifier is required on a patient specimen label for the specimen to be acceptable. The Foodborne & Waterborne Diseases Section was unable to provide a written policy and procedure that detailed this information. c. According to laboratory records, the laboratory performs and reports approximately 12,400 patient tests annually.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step

	performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on laboratory personnel interviews and Mycology quality control policies and procedures record review on December 3, 2020, the laboratory failed to have a procedure manual that included quality control procedures related to the handling of mycology quality control organisms used to monitor culture media and test systems for applicable reactivity. Findings included: a. In the Mycology Section, it was the practice of the laboratory to use quality control organisms that had been developed by the laboratory to monitor culture media and test systems for applicable reactivity. Many of these quality control organisms were described as "historic" by the laboratory because these organisms had been developed by the laboratory many years prior to their current use. The use of "historic" quality control organisms appeared to be a practice throughout the laboratory, in addition to the Mycology Section. b. The laboratory maintained no written policies and procedures that defined the handling and use of "historic" quality control organisms including when these quality control organisms expire, have deteriorated, or are of substandard quality. c. According to laboratory records, the laboratory performs and reports approximately 12,400 patient tests annually.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on laboratory personnel interviews and Mycology microscope maintenance policies and procedures record review on December 3, 2020, the laboratory failed to establish a maintenance protocol that ensures microscope performance necessary for accurate and reliable test results and test result reporting. Findings included: a. In the Mycology Section, the laboratory performed microscopic exams of isolates from patient specimens using a microscope. Such a microscopic exam was performed on an isolate from patient specimen M20D00364 on November 20, 2020. b. Although the laboratory performed maintenance on the microscope used for specimen M20D00364,

	the laboratory maintained no written protocol establishing microscope maintenance in use. c. According to laboratory records, the laboratory performs and reports approximately 12,400 patient tests annually.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on laboratory personnel interviews and Foodborne & Waterborne Disease Section bacteriology media quality control record review on December 2, 2020, the laboratory failed to maintain documentation to indicate that each batch/lot of bacteriology media used to culture patient specimens was checked when prepared or opened for positive and negative reactivity. Findings included: a. In the Foodborne & Waterborne Disease Section, the laboratory routinely checked each batch/lot of bacteriology media used to culture patient specimens when prepared or opened for positive and negative reactivity. b. However, for patient specimen M20F00044, received by the laboratory on January 6, 2020, based on information detailed on the laboratory's worksheet and media quality control records, it could not be determined as to which batch/lot of MacConkey plates were used by the Foodborne & Waterborne Disease Section to culture this patient's specimen. That is, because the laboratory maintained no documentation as to when any specific batch/lot of MacConkey plates had been placed into use, it could not be determined which batch /lot of MacConkey plates was used to culture this patient's specimen. c. According to laboratory records, the laboratory performs and reports approximately 12,400 patient tests annually.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on laboratory personnel interviews and quality assessment record review on December 4, 2020, the laboratory failed to include in its analytic systems quality assessment a review that its quality assessment mechanisms were effective. Findings included: a. Although the laboratory established and maintained an analytic systems quality assessment protocol, the analytic systems quality assessment mechanisms failed to ensure that: i. Procedure manuals included complete quality control protocols (see D5403); ii. A written microscope maintenance protocol was established (see

	D5433); and, iii. Media quality control protocols were completed for media used to culture patient specimens (see D5471). b. According to laboratory records, the laboratory performs and reports approximately 12,400 patient tests annually.