Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0643851	12/14/2022
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
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: 1. Based on laboratory personnel interviews and quality control record review on December 12, 2022 at 11:30 am, for media checks, the laboratory failed to maintain documentation to indicate that the batch of TSI reagents used to culture patient specimens, before or concurrent with the initial use, had been checked for sterility, ability to support growth, and that the physical characteristics of the reagent had not been compromised. Findings included: a. In the Salmonella serotyping section, it was the practice of the laboratory to test patient specimens using TSI reagents. b. For 2 (specimen accession numbers M22X002432 and M22X002603) of 2 randomly selected patient specimens in which the laboratory reported final Salmonella serotyping test results on November 30, 2022 and December 5, 2022, respectively, the laboratory maintained no documentation to indicate that the batch of TSI reagents used to test these patient specimens had been checked for sterility, ability to support growth, and that the physical characteristics of the media had not been compromised. c. Based on laboratory documents, the laboratory performed and reported approximately 2891 patient Salmonella serotyping test results annually. 2. Based on laboratory personnel interviews and quality control record review on December 12, 2022 at 11:30 am, for ONPG reagent checks, the laboratory failed to maintain documentation to indicate that the batch of ONPG reagents used to test patient

	specimens, before or concurrent with the initial use, had been checked for sterility. Findings included: a. In the Salmonella serotyping section, it was the practice of the laboratory to test patient specimens using ONPG reagents. b. For ONPG reagents made/received on December 6, 2022, the laboratory maintained no documentation to indicate that sterility had been checked before or concurrent with the initial use. c. Based on laboratory documents, the laboratory performed and reported approximately 2891 patient Salmonella serotyping test results annually.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: 1. Based on laboratory personnel interviews and quality control record review on December 12, 2022 at 11:30 am, the laboratory failed to maintain an information or record system that included the date of all TSI reagents quality control testing, including the identity of the personnel who performed the tests. Findings included: a. In the Salmonella serotyping section, it was the practice of the laboratory to test patient specimens using TSI reagents. b. For TSI reagents, laboratory records failed to indicate the date and the personnel who performed TSI reagent quality control checks for TSI reagents made/received on November 17, 2022. c. Based on laboratory documents, the laboratory performed and reported approximately 2891 patient Salmonella serotyping test results annually. 2. Based on laboratory personnel interviews and patient test worksheets record review on December 12, 2022 at 11:30 am, the laboratory failed to maintain an information or record system that included the dates of all specimen testing. Findings included: a. In the Salmonella serotyping section, it was the practice of the laboratory to document all patient specimens testing records using established worksheets. b. For specimen accession number M22X002432, in which the laboratory reported final Salmonella serotyping test results on November 30, 2022, the laboratory's record system failed to indicate the date(s) on which tests were performed/read. c. For specimen accession number M22X002603, in which the laboratory reported final Salmonella serotyping test results on December 5, 2022, the laboratory's record system failed to indicate which tests were performed/read on which of the multiple dates recorded. d. Based on laboratory documents, the laboratory performed and reported approximately 2891 patient Salmonella serotyping test results annually.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (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 control record review on December 12, 2022 at 11:30 am, the laboratory failed to follow policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. Findings included: a. According to the laboratory's protocol titled "Quality Assessment Manual (SOP Number MDL-MQAM-001)," quality assessment reviews of quality control records were to occur at least monthly. b. In the Salmonella serotyping section, the laboratory maintained no document to indicate that quality assessment reviews had occurred for: i.) TSI reagents made/received on July 20, 2022, July 29, 2022, August 10, 2022, August 19, 2022, September 2, 2022, September 14, 2022, September 28, 2022, October 6, 2022, October 13, 2022, October 24, 2022, November 2, 2022, November 17, 2022, and December 1, 2022. ii.) ONPG reagents made/received on December 6, 2022. c. The "Supervisor Review" section of the form for TSI and ONPG reagents for the dates listed was blank. d. Based on laboratory documents, the laboratory performed and reported approximately 2891 patient Salmonella serotyping test results 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 control record review on December 12, 2022 at 11:30 am, for ONPG reagent checks, the laboratory failed to have an analytic systems quality assessement mechanism that included a review of the effectiveness of corrective actions taken to resolve problems. Findings included: a. In the Salmonella serotyping section, it was the practice of the laboratory to test patient specimens using ONPG reagents. b. For ONPG reagents made/received on October 25, 2022, the laboratory's record indicated that quality control checks were completed on October 17, 2022, which was before this ONPG reagents was made/received by the laboratory. c. The laboratory's record also indicated that a quality assessment review of this quality control check was completed on November 1, 2022 without an indication that the date of the quality control check was before the ONPG reagents was made/received, suggesting that the laboratory's November 1, 2022 quality assessment review was ineffective. d. Based on laboratory documents, the laboratory performed and reported approximately 2891 patient Salmonella serotyping test results annually.
D5815	TEST REPORT CFR(s): 493.1291(h) When the laboratory cannot report patient test results within its established time frames, the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing.

	This STANDARD is not met as evidenced by: Based on laboratory personnel interviews and test results reporting record review on December 12, 2022 at 11:30 am, when the laboratory could not report patient Salmonella serotyping test results within its established time frame, the laboratory failed to maintain documentation to indicate that the laboratory determined, based on the urgency of the patient test requested, the need to notify the appropriate individual (s) of the delayed testing. Findings included: a. In the Salmonella serotyping section, it was the practice of the laboratory to report patient Salmonella serotyping test results within four (4) weeks of receipt of the patients' specimens. b. For specimen accession number M22X002432, the laboratory's record indicated that this patient specimen was received on October 20, 2022 for Salmonella serotyping. The laboratory's record also indicated that the final Salmonella serotyping test results were reported on November 30, 2022, more than four (4) weeks from the receipt of the patient's specimen. The laboratory maintained no documentation to indicate that the laboratory determined, based on the urgency of the patient test requested, the need to notify the appropriate individual(s) of this delayed testing. c. Based on laboratory documents, the laboratory performed and reported approximately 2891 patient Salmonella serotyping test results annually.