Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0060808	(X3) Date Survey Completed 07/10/2024
Name of Provider or Supplier San Diego County Public Health Lab	**Street Address, City, State** 5570 Overland Ave, Ste 103, San Diego, 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
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 of the laboratory's reagent materials used in the laboratory and interview with the laboratory's technical supervisor (TS) and general supervisor (GS) 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 on July 10, 2024, at approximately 3:00 pm.; no opening, preparation, or expiration date labels were used or documented for various reagents used in the Mycobacteriology laboratory. 2. The laboratory's TS and GS affirmed in an interview conducted on July 10, 2024, at approximately 3:15 p.m. that Auramine and Rhodamine reagents used for Mycobacteria stain (TB decolorizer, TB Potassium permanganate, and Auramine O), and immersion oil reagents were not labeled with the received date, opening, preparation, and expiration dates or documented in a reagent preparation log. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed approximately 2,000 Mycobacteriology test samples.
D6144	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463 The general supervisor is responsible for day-to-day supervision or oversight of the

	laboratory operation and personnel performing testing and reporting test results. This STANDARD is not met as evidenced by: Based on survey findings and deficiency cited D5415; the General Supervisor (Testing Person/ Technical Supervisor/ Laboratory Director) is herein cited for deficient practice in providing general oversight of the laboratory and personnel. Findings included: The General Supervisor (Testing Person/ Technical Supervisor/ Laboratory Director) failed to have a mechanism or practice in place to proper label reagents used in the laboratory.