Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1066369	04/04/2024
Name of Provider or Supplier	**Street Address, City, State**	
Los Angeles County	12750 Erickson Ave, Downey, 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
D2021	BACTERIOLOGY CFR(s): 493.823(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on review of Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing (PT) records for Bacteriology first event of 2024 (Q1-2024), two (2) randomly selected patients from 2/6/2024 and 3/27/2024, and interview with the laboratory director (LD) technical supervisor (TS), and compliance officer (CO); it was determined that the laboratory failed to participate the testing event which is unsatisfactory performance and resulted with a score of zero (0) for the testing event. The findings included: 1. Laboratory PT records showed the laboratory attained a score of 0% for Bacteriology testing during the Q1-2024 for the Module 5080 Enteric Pathogens which included 5 stool samples for analytes: Aeromonas, Campylobacter, E. coli 0157, Pleisomonas, Salmonella, shigella, Vibrio, and Yersinia. 2. The LD, TS, and CO affirmed on April 4, 2024, at approximately 11:30 a.m. the unsatisfactory score of 0% obtained by the laboratory for Bacteriology analytes Q1-2023 listed in 1. 3. Based on the annual test volume reported for 2024, the laboratory performed and reported approximately 284,123 bacteriology analytes.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY

	CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of patient testing records, patient final testing reports, and interviews with the laboratory director (LD) and technical supervisor (TS) on 04/04/2024 at approximately 12:30 p.m. it was determined that for one (1) out of five (5) randomly chosen patient testing records reviewed, the laboratory failed to follow written policies and procedures for specimen analytical phase testing, through completion of testing and reporting results. The findings included: 1. Review of sample testing worksheet documentation and patient's final test report [electronic medical record (EMR)], it was found that patient test result reported did not follow testing procedure and reporting policy. a. Mycology standard operating procedure indicated identification of Aerobic Actinomycete using the biochemical Lysozyme test. b. Worksheet indicated no lysozyme biochemical testing was performed to identify the isolate. c. Protocol does not indicate identification of Nocardia spp. by morphology only. d. Final report reads " Organism colony morphology consistent with Nocardia species." e. Final report did not include reference to previous isolation of the organism and that biochemical test identification on specified date occurred. 2. The LD and TS affirmed that the patient testing in the mycology laboratory for Nocardia spp identification was different than the result in the patient's EMR. 3. Based on the laboratory's annual test volume declaration signed by the LD on 4/3/2024 the laboratory performed 136 mycology isolates identification to genus or genus and species.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, five (5) randomly chosen patients records, failure to submit proficiency testing results in a timely manner, and interviews with the laboratory director, technical supervisor, and testing personnel; it was determined that the laboratory director failed to ensure the maintenance of acceptable levels of analytical and post analytical performance. See D2021 and D5203.
D6119	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(6) The technical supervisor is responsible for ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly.

	This STANDARD is not met as evidenced by: Based on interviews with the laboratory director, compliance officer, and testing personnel, review of policies and procedures, and patients' reports; it was determined that the technical supervisor failed to ensure that patient test results were not reported until the test system was functioning properly. See D5203.