Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2095005	02/14/2023
Name of Provider or Supplier	**Street Address, City, State**	
Prime Lab Inc	31344 Via Colinas, #104, Westlake Village, 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
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's test requisition, and interview with the laboratory technical supervisor on February 14, 2023, at 1:20 pm, the laboratory failed to have the time of specimen collection on the requisition. The findings include: 1. The laboratory received sputum specimen for pneumonia panel testing on Biofire instrument. According to the manufacturer, the sample is good at room temperature for 4 hours after collection. However, one sample 274457, out of 4 reviewed, did not have the collection time on the requisition. On the other hand, the laboratory did not have any information about the storage condition of the sample after collection. Therefore, the sample integrity could not be assured and thus the accuracy of the reported results. 2. The laboratory technical supervisor on February 14, 2023, at 1:20

	pm, affirmed that the requisition did not have the collection time. 3. The laboratory's testing declaration form, signed by the laboratory director on 2/10/2023, stated that the laboratory performs approximately 1,506 bacteriology tests, annually.
D5467	CONTROL PROCEDURES CFR(s): 493.1256(d)(9)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- When using calibration material as a control material, use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's quality control material, calibrator, and interview with the laboratory technical supervisor on February 14, 2023, at 12:20 pm, the laboratory failed to use different lot's control material from the calibrator. The findings include: 1. The laboratory used an LC-MS/MS method to detect various drugs in the patient sample. It generates a standard curve each time of testing. The laboratory used a calibrator to generate the standard curve, however, it used the same calibrator lot from the manufacturer as quality control material. Therefore, the validity of the test method can not be assured and might have harmed patient. 2. The laboratory technical supervisor on February 14, 2023, at 12:20 pm, affirmed that the laboratory used the calibrator material from the same lot as quality control material. 3. The laboratory's testing declaration form, signed by the laboratory director on 2/10 /2023, stated that the laboratory performs approximately 1,005 toxicology tests, annually.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's calibrator, quality control materials, test requisition and interview with the laboratory technical supervisor on February 14, 2023, at 1:20 pm, it was determined that the laboratory director failed to assure the compliance with the applicable regulations. The findings include: See D5467 and D5305.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1)

	The laboratory director must 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 Surveyor review of laboratory's calibrator, quality control materials, test requisition and interview with the laboratory technical supervisor on February 14, 2023, at 1:20 pm, it was determined that the laboratory director failed to assure the test quality. The findings include: See D5467 and D5305.