Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0914812	10/18/2023
Name of Provider or Supplier	**Street Address, City, State**	
Primex Clinical Laboratories, Inc	16742 Stagg St, Ste 120, Van Nuys, 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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's patient test records and interview with the laboratory technical supervisor on October 18, 2023, at 4:43 pm, the laboratory failed to monitor, assess, and correct problems in the general laboratory systems. The findings include: 1. The laboratory failed to monitor, assess, and, identify and correct problems in the general laboratory systems: a) It received the sample, 10066275 on July 28, 2023 for Hep B surface Ag, Ab and core Ab tests. Thirteen days later, on August 10, the laboratory reported as, specimen quantity not sufficient (QNS) to perform the tests. The lab had not rejected the sample for insufficient amount received, and 13 days later it reported as QNS. On the other hand, the lab's turnaround time for these tests is about 2 days and each test requires only 100 microliters of sample. The lab may have lost the sample during processing and handling and thus 13 days later reported as QNS without identifying the underlying problem. b) It received the sample, 10145319 for sed rate test. However, it cancelled the test due to lab error. The lab did not perform the test within the sample stability time limit. Therefore, the patient may have harmed by the lab's practice. 2. The laboratory technical supervisor on October 18, 2023, at 4:43 pm, affirmed that the laboratory did not have a system in place to monitor the problems. 3. The laboratory's testing declaration form, signed by the laboratory owner on 10/17/2023, stated that the laboratory performed approximately 4,822,055 tests, annually.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's patient test records and interview with the laboratory technical supervisor on October 18, 2023, at 4:43 pm, the laboratory director failed to ensure that the laboratory maintained quality assessment programs. The findings include: See D5291.