Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0914812	06/25/2018
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
D2075	GENERAL IMMUNOLOGY CFR(s): 493.837(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on the review of first quarter (Q1-2017) of the American Association of Bioanalysts (AAB) proficiency testing records, and interview with the technical consultant, it was determined that the laboratory failed to attain an overall testing event score of at least 80 percent is unsatisfactory performance. The findings included: a. AAB reported unsatisfactory score of 60% for Antinuclear Antibody (ANA). b. For two (2) out of two (2) random patient sampling test results reviewed covering period from 12/11/2017 and 12/19/2017, the laboratory reported ANA tests approximately during the time the laboratory received the unsatisfactory proficiency testing score. c. The technical consultant affirmed (6/25/2018, 17:30) that the laboratory received the above unsatisfactory proficiency testing score.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on the review of first quarter (Q1-2018) of the American Association of Bioanalysts (AAB) proficiency testing records, and interview with the technical consultant, it was determined that the laboratory failed to least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not

	included in subpart I of this part. a. Q1-2018, AAB reported unsatisfactory score of 0% for H. Pylori antigen detection. b. For two (2) out of two (2) random patient sampling test results reviewed covering period from 6/26/2016 and 1/19/2018, the laboratory reported H. Pylori tests approximately during the time the laboratory received the unsatisfactory proficiency testing score. c. The technical consultant affirmed (6/25/2018, 17:30) that the laboratory received the above unsatisfactory proficiency testing score.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records from the American Association of Bioanalyts (AAB) for first quarter Q1-2017 and first quarter Q1-2018, random patient sampling test results, and interview with the technical consultant, it was determined that the laboratory director failed to ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. See D2075 and D5217.