Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0914812	04/08/2026
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
D0000	An on-site re-certification survey was performed on April 8, 2026, the laboratory was found not in compliance with the following CONDITION LEVEL DEFICIENCIES D2016 - 42 C.F.R. 493.803 Condition: Successful [proficiency testing] participation; and D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on the on-site review of laboratory's proficiency testing (PT) results from the College of American Pathologists (CAP) and an interview with the technical consultant on April 8, 2026, the laboratory failed to successfully participate in a

	proficiency testing program approved by HHS for each specialty, subspecialty and analyte or test in which the laboratory is certified under CLIA, the laboratory failed to successfully participate in the analyte troponin I for the 2025-1 and 2025-2 events resulting in unsuccessful performances. See D2096.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) (f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on the on-site survey on April 8, 2026, an interview with the technical consultant and surveyor's review of the laboratory's proficiency testing records from the College of American Pathologists (CAP), the laboratory failed to achieve satisfactory performance for two consecutive events (2025-1 and 2025-2) for the analyte Troponin I (specialty Chemistry). The findings include: 1. Troponin I 0% - 2025 first testing event; Troponin I 0% - 2025 second testing event. A review of the 2025 scores from the laboratory's proficiency testing documentation confirmed the above findings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on the on-site survey on April 8, 2026, review of the College of American Pathologists (CAP) proficiency testing (PT) records for 2025-1 and 2025-2 events, the laboratory director failed to provide overall management and direction of the laboratory services to ensure successful participation of the proficiency testing. Refer to D6016.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on an on-site survey on April 8, 2026, review of the laboratory's proficiency testing reports from the College of American Pathologists (CAP) for 2025-1 and 2025-2 events and an interview with the technical consultant, the laboratory director failed to ensure successful proficiency testing participation as required in this subpart. Refer to D2096