Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2007334	08/05/2026
Name of Provider or Supplier	**Street Address, City, State**	
Tlc Laboratory	13422 Newport Ave, Suite L, Tustin, 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	A proficiency testing desk review survey was performed on August 5, 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 review of the Certification and Survey Provider Enhanced Reporting (CASPER) - 0155D and American Proficiency Institute (API) records for 2025 and 2026 testing events, 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 high-sensitivity C-Reactive Protein (hs-CRP) and Free Thyroxine analytes resulting in unsuccessful performances. The findings include: 1. The laboratory failed to achieve satisfactory performances for hs-CRP analyte for at least three consecutive events in General Immunology specialty. See D2084 2. The laboratory failed to achieve satisfactory performances for Free Thyroxine analyte for three testing events in Chemistry specialty. See D2107. .
D2084	GENERAL IMMUNOLOGY CFR(s): 493.837(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 review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and American Proficiency Institute (API) report, the laboratory failed to achieve satisfactory performance for at least three consecutive events (2025-1, 2025-2, 2025-3, and 2026-1) for the analyte high-sensitivity C-Reactive Protein (hs-CRP) (specialty General Immunology): The finding include: 1. hs-CRP 40% - 2025 first testing event; hs-CRP 20% - 2025 second testing event; hs-CRP 60% - 2025 third testing event; hs-CRP 20% - 2026 first testing event. A review of the 2025 & 2026 scores from American Proficiency Institute (API) confirmed the above findings.
D2107	ENDOCRINOLOGY CFR(s): 493.843(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 review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and American Proficiency Institute (API) report, the laboratory failed to achieve satisfactory performance for three testing events (2025-2, 2025-3, and 2026-2) for the analyte Free Thyroxine (specialty Chemistry): The finding include: 1. Free Thyroxine 20% - 2025 second testing event; Free Thyroxine 40% - 2025 third testing event; Free Thyroxine 40% - 2026 second testing event. A review of the 2025 & 2026 scores from American Proficiency Institute (API) 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 a proficiency testing desk review of the CASPER 0155D report and American Proficiency Institute (API) records for several testing events in 2025 and 2026, 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 a proficiency testing desk review of the CASPER 0155D report and American Proficiency Institute (API) records for several testing events in 2025 and 2026, the laboratory director failed to ensure successful proficiency testing participation as required in this subpart. The findings include: 1. The laboratory failed to achieve satisfactory scores for the high sensitivity C-Reactive Protein analyte in the 2025-1, 2025-2, 2025-3, and 2026-1, consecutive testing events. See D2084. 2. The laboratory failed to achieve satisfactory scores for the Free Thyroxine analyte in the 2025-2, 2025-3, and 2026-2 testing events. See D2107.