Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0415981	10/05/2026
Name of Provider or Supplier	**Street Address, City, State**	
Duly Health And Care - Glen Ellyn Lab	430 Pennsylvania Ave, Glen Ellyn, IL	

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	Based on a desk review of proficiency testing records from the Certification and Survey Provider Enhanced Reporting (CASPER) database and verified with the proficiency testing provider, the laboratory was found to be out of compliance with the 42 C.F.R. Part 493 CLIA requirements for the following CONDITION level deficiencies: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing]; 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 a proficiency testing desk review of the Certification and Survey Provider

	Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and American Proficiency Institute (API) Proficiency Testing (PT) records, the laboratory failed to successfully participate in the API PT program for the hematology analyte Hematocrit for two of three consecutive PT events in 2025 and 2026 (Event 3 of 2025 and Event 2 of 2026) resulting in the initial unsuccessful PT performance. Refer to D2130.
D2130	HEMATOLOGY CFR(s): 493.851(f) (f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a proficiency testing desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and American Proficiency Institute (API) Proficiency Testing (PT) records, the laboratory failed to achieve satisfactory performance for the hematology analyte Hematocrit for two of three consecutive PT events in 2025 and 2026 (Event 3 of 2025 and Event 2 of 2026) resulting in the initial unsuccessful PT performance. Findings include: 1. Review of the CASPER Report 0155D, generated on 10/02/2026, the laboratory received the following unsatisfactory scores for the hematology analyte Hematocrit. Hematocrit Event 3, 2025 - 60% Unsatisfactory Event 2, 2026 - 0% Unsatisfactory 2. Review of API PR evaluation reports (Hematology/Coagulation) confirmed the above unsatisfactory scores that resulted in the initial unsuccessful PT performance for the hematology analyte Hematocrit.
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 Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and American Proficiency Institute (API) Proficiency Testing (PT) records, the laboratory director failed to ensure successful participation in a Health and Human Services (HHS) approved PT program for hematology analyte Hematocrit for two of three consecutive PT events in 2025 and 2026 (Event 3 of 2025 and Event 2 of 2026) resulting in the laboratory's initial unsuccessful PT performance. 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 Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and American Proficiency Institute (API) Proficiency Testing (PT) records, the laboratory director failed to ensure successful participation in a Health and Human Services (HHS) approved PT program for hematology analyte Hematocrit for two of three consecutive PT events in 2025 and 2026 (Event 3 of 2025 and Event 2 of 2026) resulting in the laboratory's initial unsuccessful PT performance. Refer to D2130.