Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D1085079	02/05/2026
Name of Provider or Supplier	**Street Address, City, State**	
Duly Health And Care - Rickert Lab	808 Rickert Dr, Naperville, 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
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on direct observation, the Food and Drug Administration (FDA)'s laboratory test complexity database, review of laboratory records, and interview with the technical supervisor (TS), the laboratory failed to establish the performance specifications for one of one Alcor iSED ELITE erythrocyte sedimentation rate analyzer (serial number: 5774) prior to reporting patient test results from 07/01/25 to January 2026, affecting 3,420 patient tests. Findings include: 1. During the laboratory tour on 02/04/2026, at 1:11 pm, the surveyor identified one Alcor iSED ELITE erythrocyte sedimentation rate analyzer (serial number: 5774). 2. Review of the FDA's laboratory test complexity database found that the Alcor iSED ELITE erythrocyte sedimentation rate analyzer was not categorized by the FDA. 3. Review of laboratory validation records for the Alcor iSED ELITE erythrocyte sedimentation rate analyzer (serial number: 5774) revealed the laboratory failed to establish all the required performance specifications of an analyzer not cleared by the FDA including: - Analytical sensitivity. - Analytical specificity to include interfering substances. - Reportable range of test results for the test system. - Any other performance

	characteristic required for test performance 4. On 02/05/2026, at 12:18 pm, the TS confirmed the laboratory failed to establish the required performance specifications for one of one Alcor iSED ELITE erythrocyte sedimentation rate analyzer (serial number: 5774) prior to releasing patient results. 5. Interview with TS on 02/05/26 at 1: 00 pm revealed 3,420 patient tests were performed on the Alcor iSED ELITE erythrocyte sedimentation rate analyzer (Serial number: 5774) from the date of implementation on 7/1/25 to January of 2026.