Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0397042	08/14/2024
Name of Provider or Supplier	**Street Address, City, State**	
Northlakes Community Clinic	15954 Rivers Edge Dr, Hayward, WI	

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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory verification records and procedures for one of one new analyzer and interview with the two technical consultants, the laboratory did not document evaluation of the Diesse MINI-CUBE ESR (Erythrocyte Sedimentation Rate) analyzer precision or reference interval (normal range) and did not evaluate the full reportable range prior to reporting patient results starting in July 2023. Findings include: 1. Review of the verification records for the Diesse MINI-CUBE ESR analyzer showed the laboratory director signed a summary sheet on January 4, 2023, referencing the laboratory's comparison studies between the MINI-CUBE and the ESR AutoPlus analyzers. The summary sheet and attached comparison study showed no evaluation of precision or the reference interval for the analyzer. The comparison study included samples with results between 5 and 50 mm/hour. 2. The laboratory procedure, 'Diesse MINI-CUBE ESR Automated Method', stated the laboratory's reportable range was 0 - 140 mm/hour. 3. Interview with the two technical consultants on August 14, 2024, at 10:30 AM confirmed the verification records did not include precision data or show the director evaluated precision for the Diesse MINI-CUBE ESR analyzer and did not show evaluation of reference intervals. Further interview confirmed the laboratory had not evaluated the full reportable range prior to starting patient testing.