Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D2117500	06/08/2026
Name of Provider or Supplier	**Street Address, City, State**	
Bennett Cancer Center Laboratory	1 Hospital Plaza, Stamford, CT	

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) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 observation, record review and staff interview, the laboratory failed to follow its established policies and procedures for method performance verification and document precision, reportable range and reference range verification prior to placing the instrument into use in the specialty of hematology. Findings include: 1. Surveyor observation on 06/08/2026 at 2:30 PM of the hematology laboratory revealed two of two 'Sysmex XN-10 Automated Hematology Analyzers' in use. 2. Record review on 06/08/2026 of the laboratory's 'Sysmex XN-10 Automated Hematology Analyzers' validation binder data revealed the following: a. Accuracy and method comparison studies for two of two 'Sysmex XN-10 Automated Hematology Analyzers' completed on 02/13/2025. b. Lack of documentation of the following required validation steps for a nonmodified FDA cleared test system: i. Precision. ii. Reportable ranges. iii. Verification of the manufacturer's reference intervals. c. Lack of documentation of the Laboratory Director's review and/or approval of the validation studies. 3. Record review on 06/08/2026 of the laboratory's 'Method Validation Verification' standard operating procedure revealed the following required verification steps prior to placing the instrument into use: a. 'Precision'. b. 'Reference range verification'. c. 'Reportable range verification'. d. 'Calibration verification'. 4. Staff interview on 06/08/2026 at 1:30 PM with the laboratory's general supervisor

	confirmed the above findings. 5. The laboratory performs 23,326 complete blood count tests annually in the specialty of hematology.