Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0906022	09/20/2023
Name of Provider or Supplier	**Street Address, City, State**	
North Shore Hematology Oncology Associates	2330 Eastchester Road, Bronx, NY	

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
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory procedures, the i-STAT instruction manual, and interviews with the laboratory supervisor as well as Quality Assurance (QA) personnel, the laboratory failed to completely document monthly i-STAT cartridge quality control results. Findings: 1. Review of the monthly i-STAT cartridge log indicated that i-STAT cartridges were evaluated and approved however respective results or ranges were not included with the documentation. 2. The new control and lot cartridge log did not include temperature strip result documentation. 3. Confirmed findings by interviews with the lab supervisor and QA personnel on September 20, 2023, at 11:30 A.M.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

	This STANDARD is not met as evidenced by: Based on the review of the laboratory procedures, lack of documented corrective action, and interviews with the laboratory supervisor as well as QA personnel, the laboratory failed to investigate and perform corrective action for i-STAT Tricontrols that failed quality control testing. Findings: 1. On July 11, 2023, TCO2 Level 1 (301157) and Level 2 (311151) controls failed. 2. Monthly QA review did not document i-STAT Tricontrol QA corrective action was performed. 3. Approximately twenty-four patient samples were tested between July 11, 2023, through August 18, 2023, during the period of failed quality controls. 4. Confirmed the findings by interview with the lab supervisor and QA personnel on September 20, 2023, at 11:30 A.M.