Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2231456	(X3) Date Survey Completed 07/01/2022
Name of Provider or Supplier North Shore Hematology Oncology Associates Pc	**Street Address, City, State** 501 Hawkins Ave, Lake Ronkonkoma, 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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy and procedure manual, QC records for the Influenza A&B and Strep A, and an interview with the general supervisor, the laboratory failed to follow external Quality Control (QC) policy. FINDINGS: 1. The laboratory failed to perform external QC every new lot or new shipment as stated in laboratory's policy. 2. The external QC log of Influenza A&B and Strep A are not available for review. 3. The general supervisor confirmed during interview on 7/1/22 at approximately 11am.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of the laboratory records and confirmed in an interview at the time

	of this survey with the general supervisor, the laboratory director failed to ensure that the QC program for the Influenza A&B and Strep A maintained to assure quality of laboratory services. Refer to D5401.