Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2223211	(X3) Date Survey Completed 07/23/2024
Name of Provider or Supplier North Shore Hematology Oncology Associates Pc	**Street Address, City, State** 1500 Route 112, Building , Suite 102, Port Jefferson Station, 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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the Quality Assessment (QA) policy, QA record reviews, as well as interview with the Technical Supervisor (TS), the laboratory failed to comply with frequency of bi-annual QA performance review. FINDINGS: 1. There was no documentation of 2023 bi-annual QA review. 2. This was contrary to instructions indicated in the current, approved QA policy. 3. TS confirmed findings on July 23, 2024, at approximately 12:30 P.M. PLEASE NOTE: THIS IS A RECITED DEFICIENCY FROM SURVEY CONDUCTED JUNE 3, 2022.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by:

	Based on review of the current, approved QA procedure, QA record reviews, as well as interview with the TS, the laboratory director (LD) failed to comply with QA for all phases for the general laboratory system. Refer to D5291. PLEASE NOTE: THIS IS A RECITED DEFICIENCY FROM SURVEY CONDUCTED ON JUNE 3, 2022.