

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2223211	(X3) Date Survey Completed 06/03/2022
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	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Quality Assessment (QA) policy, the laboratory failed to establish frequency of QA policy and perform QA review. FINDINGS: 1. 2021 annual QA documentation was not available for review. 2. 2021 annual QA review not performed confirmed with an interview with technical supervisor on 6/3/3022 about 11:30am.</p>
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assessment (QA) procedure, it failed to establish frequency of QA review and confirmed in an interview with the laboratory</p>

technical supervisor, the laboratory director failed to establish a written QA for all phases for the general laboratory system. Refer to D5291.