

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2101355	(X3) Date Survey Completed 02/15/2024
Name of Provider or Supplier North Shore Hematology-Oncology Associates Pc	Street Address, City, State 72 East Main Street, Babylon, 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
D5783	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of hematology analyzer quality control (QC) reports and interview with the Quality Assurance (QA) Coordinator, the laboratory failed to perform and document corrective action for analyzer QC report accuracy bias flags. Findings: 1. The Sysmex Poch 100i (serial number: #G5121) hematology analyzer QC Lot #3164 report indicated, "This report has accuracy bias code for RBC." 2. The Sysmex Poch 100i hematology analyzer QC Lot#2193 report indicated, "This report has accuracy bias code for HCT." 3. There was no documentation of corrective action performed for the respective QC report accuracy bias flags. 4. This is contrary to instructions indicated in the current, approved North Shore Hem Oncology dba NY Cancer & Blood standard operating procedures (SOPs). 5. Confirmed findings by interview with QA coordinator on February 15, 2024, at approximately 11:00 A.M.</p>
D6020	<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</p>

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 review of the laboratory records and interview with the QA Coordinator, the laboratory director (LD) failed to ensure compliance with the hematology testing QC program to assure quality of laboratory services. Refer to D5783.