

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0926424	(X3) Date Survey Completed 05/06/2019
Name of Provider or Supplier North Shore Hematology-Oncology Associates, Pc	Street Address, City, State 375 East Main Street - Suite 21, Bayshore, 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
D3037	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor review of College of American Pathologists (CAP) Proficiency Testing (PT) records for calendar years 2017 and 2018 and confirmed in an interview with the laboratory QA coordinator, the laboratory failed to retain CAP PT records and documentation to include signed attestation forms, test result forms, PT test result print-outs and a signed PT summary reports for the third event 2017 hematology challenges.</p>
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on a surveyor review of hematology calibration records and an interview with</p>

the laboratory QA coordinator, calibration of the hematology analyzers was not performed at the frequencies required by the manufacturer of the Sysmex 1000i and POCH 100i hematology analyzers. FINDINGS: 1. The laboratory has two hematology analyzers, Sysmex XS1000i and POCH 100i. The manufacturer of the hematology analyzers and the laboratory's calibration policy require analyzers calibration every six months. 2. The documentation for the POCH 100i analyzer calibration available for review was for calibration performed in August 2017, 10/5/18 and 4/6/19. The POCH 100i hematology analyzer was therefore out of calibration from February 2018 through 10/4/18. 3. The documentation for the Sysmex XS 1000i analyzer calibration available for review was for calibration performed on 8/8/17, 1/31/18, 1/18/19 and 4/6/19. The Sysmex 1000i hematology analyzer was therefore out of calibration from 8/1/18 through 1/17/19. 4. Approximately 400 patient specimens were tested and reported for hematology during the above time frame when the POCH 100i and Sysmex 1000i analyzers were out of calibration.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
Based on a surveyor's review of the personnel files and interview with the QA coordinator, the laboratory director, acting as the technical consultant, failed to perform semi-annual and annual competency evaluations for the one of four testing persons in calendar year 2018 and up to this survey date. The testing person was hired in July 2017.