

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0934129	(X3) Date Survey Completed 02/27/2018
Name of Provider or Supplier North Shore Hematology Oncology Associates Pc	Street Address, City, State 640 County Road 39, Southampton, 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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on a surveyor review of the calibration and quality control (QC) records for the hematology analyzers, and interview with the two laboratory supervisors, the laboratory failed to retain QC and calibration records for one of two hematology analyzers from May 18, 2016 through July 25, 2017. FINDINGS: The laboratory used two Coulter AcT Diff analyzers from May 18, 2016 through 7/25/17. On February 27, 2018 at approximately 11:00 AM, the two supervisors confirmed that the binder containing the QC and calibration records for one of the two Coulter AcT Diff analyzers was misplaced during the laboratory relocation.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of College of American Pathologist (CAP) Proficiency Testing (PT) reports and confirmed in an interview with the two laboratory supervisors at the time of this survey, the laboratory failed to evaluate, perform and document remedial action for the PT score 0% for hematology Cell ID for the third event in 2017.</p>

D5437

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(a)

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.

This STANDARD is not met as evidenced by:

Based on a surveyor's review of hematology calibration records and interview with the two laboratory supervisors, calibration of the hematology analyzers was not performed at the frequencies required by the laboratory's calibration protocol and by the manufacturer of the analyzers. FINDINGS: 1. The laboratory used two Coulter AcT Diff analyzers up to 7/25/17. Documentation of one of the two Coulter AcT Diff analyzer (infusion room analyzer) was not available for review from 5/18/16 through 7/25/17. 2. The laboratory validated and initiated the new Sysmex XS Series 1000i and the new POCH-100i hematology analyzers in 7/26/17. Calibration records available for review for the Sysmex XS Series 1000i and the POCH-100i analyzers were for calibration done as part of validation study in 7/26/17. The analyzers therefore, were out of calibration from 1/27/18 through the survey date 3. Approximately 2000 patient specimens were tested and reported for hematology during the above time period.