

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0132959	(X3) Date Survey Completed 07/03/2018
Name of Provider or Supplier North Shore Hematology-Oncology Associates Pc	Street Address, City, State 12 East 86th Street, Suite 4, New York, 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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory procedure manual and an interview with the laboratory manager, the laboratory failed to have a complete procedure manual to include a procedure for lot to lot verification of new control material used on the ABX Micros 60 and the ABX Pentra 60 +C hematology analyzers.</p>
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p>

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of QC records and an interview with the laboratory manger/testing person, the laboratory failed to perform and document the quality control results for iron stains. Finding included; It was confirmed with the laboratory manager/testing person on July 2, 2018 at approximately 1:15 PM that the laboratory failed to perform and document the positive QC results for iron stains performed on the following days of testing: September 10, 26, 2017 November 30, 2017 January 11, 18, 2018 March 29, 1018 June 12, 2018 Approximately 7 patient slides were stained and test results reported for iron staining.

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

1) Based on a review of hematology quality control (QC) records and an interview with the laboratory manager/testing person, the laboratory failed to ensure that hematology QC results performed on the Pentra 60 + C hematology analyzer were within acceptable range prior to testing patient specimens. Findings Include: It was confirmed with the laboratory manager/testing person on July 3, 2018 at approximately 1:00 pm, that the laboratory tests three levels of QC material. a) The low control for RBC's and Hgb's were out of acceptable range and remediation was not performed on the following days: August 2, 3, 4, 7, 8, 9, 10, 11, 14, 15, 16, 17, 18, 25, 29, 30, 2018. b) On May 1, 2018, the laboratory failed to perform remediation when both the normal and high control for Hgb was out of acceptable range. 2) Based on a review of hematology QC records and an interview with the laboratory manager /testing person, the laboratory failed to have hematology QC results available for review for the ABX Micros 60 from November 1, 2018 through December 31, 2018. Approximately 1620 patient specimens were tested and results reported during that time period for all citations. This is a repeat deficiency from the last survey of July 19, 2016 .

D5893

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1299(b)(c)

(b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities.

	<p>This STANDARD is not met as evidenced by: Based on a review of the Quality Assessment (QA) policy and an interview with the laboratory manager/testing person, the laboratory failed to follow their QA policy and perform a review for the acceptance of the two of three controls that were constantly accepted for the month of August 2017.</p>
<p>D6093</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of QC records and an interview with the laboratory manager/testing person, the laboratory director failed to ensure that the QC program for hematology was followed to assure quality laboratory services. Refer to D5473, D5481.</p>
<p>D6094</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory procedure manual and an interview with the laboratory testing person, the laboratory failed to have a complete procedure manual to include a procedure for lot to lot verification of new control material used on the ABX Penra +C and the ABX Micros 60 hematology analyzer. Refer to D5403, D5893.</p>