

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2112314	(X3) Date Survey Completed 02/02/2024
Name of Provider or Supplier Novant Health Cancer Institute Ballantyne	Street Address, City, State 10905 Providence Road West, Charlotte, NC	
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 review of laboratory procedures, review of laboratory calibration records and interview with technical consultant (TC) 2/2/24, the laboratory procedure manual failed to include the type and levels of quality control (QC) reagent used for the Sysmex XN550 hematology analyzer and failed to include the types and levels of QC and calibration reagents used for the ACE Axcel chemistry analyzer. 1. The laboratory procedure manual failed to include the type and levels of QC reagent used for the Sysmex XN550. Findings: Review of laboratory procedure "Sysmex XN-550" revealed on Page 4 "Commercial Control Material XN analyzers...13. XN CHECK or</p>

XN-L CHECK....Page 6. Quality Control (QC)...Three (3) levels of control material will be processed each day prior to patient testing...". During interview at approximately 12:00 p.m. the TC stated they use XN-L CHECK reagent for QC and the levels are L1, L2 and L3. 2. The laboratory procedure manual failed to include the types and levels of QC and calibration reagent used for the ACE Axcel chemistry analyzer. Findings: Review of laboratory procedure "ACE Axcel Chemistry Analyzer" revealed on Page 2 "Controls...Controls are stored refrigerated....Test Procedure...Quality Control...A minimum of two levels of control material will be processed each day...Page 4...Calibration...Calibration is performed with a new lot number or reagent, and/or when new parameters are defined for a particular test, when the current calibration expires (refer to analyte package insert),". Review of calibration records for the ACE Axcel Chemistry Analyzer revealed the laboratory performs calibrations using 1 level of calibration reagent repeated 3 times.