





Memorandum Core #221

To: UNC Health System Attending Physicians, Housestaff, Nursing Coordinators, Department Heads and Supervisors

From:  Herbert C. Whinna, MD, PhD; Medical Director, McLendon Clinical Laboratories
 Nichole Korpi-Steiner, PhD; Director, UNCH POC Testing

Date: April 3, 2025

SUBJECT: Change from ROTEM® -to-Quantra® for Whole Blood Viscoelastic Testing

After discussion and collaboration with Surgery and Anesthesiology, UNC Medical Center McLendon Clinical Laboratories Core Laboratory will implement a change from ROTEM® -to-Quantra® for whole blood viscoelastic testing on 8-Apr-2025 starting at approximately 8:30 am.

While ROTEM® and Quantra® are similar, they are not identical technologies. The Quantra® is a cartridge based system with two tests available: “QUANTRA QPLUS [LAB10224]” and “QUANTRA QSTAT [LAB10225]” with the manufacturers stated “Intended Use/Indications for Use” and “Known Interfering Substances” shown below:

QUANTRA QPLUS [LAB10224]

Intended Use/Indications for Use

The QPlus® Cartridge (Cartridge) is intended for in vitro diagnostic use to provide indications of the coagulation state of a venous or arterial whole blood sample. The QPlus Cartridge is a multi-channel cartridge to be used with the Quantra® Hemostasis Analyzer (Quantra). Tests performed with the QPlus Cartridge, described below, use citrated whole blood samples:

The QPlus Cartridge is intended for use by trained professionals at the point-of-care and in clinical laboratories to evaluate the viscoelastic properties of whole blood by means of the following functional parameters: Clot Time (CT), Clot Time with Heparinase (CTH), Clot Stiffness (CS), Fibrinogen Contribution to Clot Stiffness (FCS), Platelet Contribution to Clot Stiffness (PCS), and Clot Time Ratio (CTR).

The QPlus Cartridge is indicated for use with patients 18 years of age or older where an evaluation of their blood coagulation properties is desired. Coagulation evaluations are commonly used to assess clinical conditions in surgery (e.g., cardiovascular and orthopedic surgeries) to assess risk of hemorrhage and thrombosis before, during, and following the procedure.

Results obtained with the QPlus Cartridge should not be the sole basis for patient diagnosis.

Known Interfering Substances

As expected and per design by manufacturer, the following substances showed significant effects on QPlus parameters in testing:

- Heparin (6U/mL) demonstrated an effect on CT but had no effect on other QPlus Cartridge parameters.

- Protamine sulfate demonstrated an effect on CT and CTR in heparinized samples (5U/mL) with effects starting at 30 µg/mL.
- The direct oral anticoagulants rivaroxaban and dabigatran demonstrated a dose response effect starting at concentrations greater than 25 ng/mL.
- Hemodilution demonstrated a dose response effect at dilutions greater than 10%.
- Increasing hematocrit levels in the range of <20% to >40% generated a decrease in most QPlus results.

QUANTRA QSTAT [LAB10225]

Intended Use/Indications for Use

The QStat Cartridge is a multi-channel cartridge that provides semi-quantitative indications of the coagulation and clot lysis state of a 3.2% citrated venous or arterial whole blood sample using the Quantra Hemostasis Analyzer. The QStat Cartridge includes tests to assess coagulation via the intrinsic and extrinsic pathways and includes a test with tranexamic acid to evaluate clot lysis characteristics. The QStat Cartridge is intended for in vitro diagnostic use by trained professionals at the point-of-care and in clinical laboratories to evaluate the viscoelastic properties of whole blood by means of the following functional parameters: Clot Time (CT), Clot Stiffness (CS), Fibrinogen Contribution to Clot Stiffness (FCS), Platelet Contribution to Clot Stiffness (PCS), and Clot Stability to Lysis (CSL).

The QStat Cartridge is indicated for the evaluation of blood coagulation and clot lysis in patients age 18 years and older to assess possible hypocoagulable and hypercoagulable conditions in trauma and liver transplantation procedures.

Results obtained with the QStat Cartridge should not be the sole basis for patient diagnosis.

Known Interfering Substances

As expected and per design by manufacturer, the following substances showed significant effects on QStat parameters in testing:

- The anti-fibrinolytic agents TXA and EACA demonstrated an effect at concentrations greater than 1 µg/mL and 10 µg/mL respectively in fibrinolytic samples.
- The direct oral anticoagulants rivaroxaban and dabigatran demonstrated a dose response effect starting at concentrations greater than 25 ng/mL.
- Hemodilution demonstrated a dose response effect at dilutions greater than 10%.
- Increasing hematocrit levels in the range of 13 to 55% generated a decrease in most QStat results with effects starting at hematocrit changes of >2%.

*****NOTE: During validation it was found that putting samples through the pneumatic tube system caused errors in testing. Therefore, ALL SAMPLES MUST BE HAND DELIVERED TO THE CORE LABORATORY. Any sample received via the pneumatic tube system will be canceled.*****

Manufacturer led training by on Quantra® Clinical Concepts, Interpretation and Application is ongoing for clinicians for both QPlus® and QStat® cartridges. Summaries of this information can also be found on the McLendon Clinical Laboratories' testing website for QPlus® and QStat® (<https://www.unccmedicalcenter.org/mclendon-clinical-laboratories/available-tests/>).

There is a remote viewing option for Quantra® currently being implemented by ISD, but will not be ready when Quantra® testing commences. We will communicate the details of access and use once it is implemented.

Please contact Dr. Whinna (Herbert.Whinna@unchealth.unc.edu; 984-974-1500) or Dr. Korpi-Steiner (Nichole.Korpi-Steiner@unchealth.unc.edu; 984-974-1498) for questions concerning the laboratory tests.