5/ REAGENT PREPARATION AND STORAGE

- **Preparation**
  Reconstitute each vial (Reagent 1, 2, 3 or 4) with 1 ml of distilled water.
  Allow the reconstituted material to stand at room temperature (18-25 °C) for 30 minutes followed by swirling of the vial before use.

- **Storage**
  The reagents in unopened vials are stable until the expiration date indicated on the box label, when stored at 2-8 °C.
  Once reconstituted, Reagents 1, 2, 3 and 4 remain stable for 8 hours on STA®-R and STA Compact®.
  Do not to freeze.

6/ REAGENTS AND EQUIPMENT REQUIRED BUT NOT PROVIDED

- **STA®- Rivaroxaban Calibrator Kit**
  Contains:
  - 3 x 1-ml Vials of Reagent 1 (STA®- Rivaroxaban Calibrator 0)
  - 3 x 1-ml Vials of Reagent 2 (STA®- Rivaroxaban Calibrator 1)
  - 3 x 1-ml Vials of Reagent 3 (STA®- Rivaroxaban Calibrator 2)
  - 3 x 1-ml Vials of Reagent 4 (STA®- Rivaroxaban Calibrator 3)
  (REF 00704US)

7/ SPECIMEN COLLECTION AND TREATMENT

- **Sample collection**
  Collection must be in accordance with the recommendations for haemostasis tests.
  - Blood (9 vol.) is collected in 0.109 M (i.e., 3.2 %) trisodium citrate anticoagulant (1 vol.).
  - Centrifugation: 15 minutes at 2000-2500 g.
  - Plasma storage: 6 hours at 20 ± 22 °C.

8/ PROCEDURE

8.1. Assay reagents

Prepare the STA® - Liquid Anti-Xa reagents as indicated on the package insert of this kit.

8.2. Assay calibration

Assay calibration is performed with Reagents 1, 2, 3 and 4 of the STA®- Rivaroxaban Calibrator Kit.

8.3. Plasma to be tested

Plasmas are tested undiluted. They are loaded in the instrument (see the Reference Manual of the analyzer model). Then select the test(s) to be performed.

8.4. Quality control

It is necessary to run controls in order to ensure accuracy and reproducibility of the results. Use STA® - Rivaroxaban Control. Prepare these controls and scan the information contained in the barcodes printed in the Analyst Value insert into the instrument. These controls are used as undiluted.

8.5. Assay

Refer to the “Standardized Operating Procedures” of the instrument for full details on how to proceed from this point. The rivaroxaban assay of the plasmas to be tested is automatically carried out by the analyzer at 405 nm as soon as the samples have been loaded.

9/ RESULTS

The rivaroxaban level (in ng/ml) of the plasmas being tested is displayed in the “Test Status/Test Panel” screen of the analyzer (see the Reference Manual).

Ensure that the values obtained for the controls are within the ranges stated in the Analyst Value insert provided in the control box. If the control values are outside the stated ranges, check all components of the test system to ensure that all are functioning correctly, i.e., assay conditions, reagents, calibration, integrity of the plasmas being tested, etc. If necessary, repeat the assays.

10/ LIMITATIONS

- Other anticoaguants (UFH, LMWH, fondaparinux...) can interfere with the assay.

- The method is insensitive to the following substances: Hemoglobin (up to 2.0 g/l), unconjugated bilirubin (up to 200 mg/l) - 342 µmol/l) and triglycerides (up to 10 g/l).

11/ PERFORMANCE CHARACTERISTICS

11.1. Characteristics of the calibrators

The level of rivaroxaban of Reagents 2, 3 and 4 may vary from one lot to another, but is clearly indicated in ng/ml for each lot (see the Analyst Value insert provided in the box).

This level is determined by high-performance liquid chromatography-mass spectrometry (HPLC-MS).

11.2. Characteristics of the method

- **Detection Threshold - Working Range**
  The detection threshold is 25 ng/ml and the linearity range extends to 500 ng/ml.

- **Precision**
  Precision studies were performed using samples containing rivaroxaban (22 days, 2 runs per day) on STA®-R with STA®- Liquid Anti-Xa. The following results have been obtained: