

# Factor IXa Control

REF	Catalogue number	9588
LOT	Batch code	HKQ1542
23	Use by	2023 10
X	Upper limit of temperature	-20°C

Activity after reconstitution with 2.0 mL water:

## Acceptance range 0.41 – 0.61 mIU/mL

The above Factor IXa activity applies only to Lot#HKQ1542.

### 1. INTENDED USE

For In Vitro Laboratory Use Only – Not for Diagnostic Use

The FIXa Control is intended for use with the Rox FIX-A Kit, Ref 950030 (Rossix AB).

#### 2. PROPERTIES

Lyophilized preparation of human Factor IXa calibrated against the 2<sup>nd</sup> International standard for Activated Blood Coagulation Factor IXa (FIXa), Human, NIBSC code 14/316 using the Rox FIX-A kit Ref 950030.

#### 3. HANDLING

Allow the ampoule to warm to room temperature before reconstitution. Reconstitute with 2 ml of water of a quality of at least NCCLS Type II water or Ph. Eur. water for injection and leave to stand at room temperature for at least 5 min with intermittent gentle mixing prior to use.

#### 4. PACKAGE

One package contains 10 vials.

#### 5. STABILITY

A reconstituted vial is stable for 8 hours at 2-8°C. An unopened vial is stable until the expiry date printed on the label.

#### 6. STORAGE

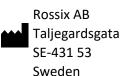
Unopened vials should be stored at or below -20°C.

#### 7. CAUTION

#### This preparation is not for administration to humans.

The product contains material of human origin. Although the starting material was tested prior to initiation of the manufacturing process, and was found negative for HBsAg, anti-HIV and HCV caution should be used when handling this material. As with all materials of biological origin, this preparation should be regarded as potentially hazardous to health. It should be used and discarded according to your own laboratory's safety procedures. Such safety procedures should include the wearing of protective gloves.

#### 8. CONTACT INFORMATION



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Rossix AB operates an ISO 13485 Medical Devices Quality Management System certified by BSI.