

# Product Change Notification

## Rox Factor IX

Date: March 01, 2012  
Product: Rox Factor IX – Ref 900020

Description of Change: Substitution of bovine Factor XIa with human Factor XIa in Reagent B, classified as a minor change.

Schedule of Change: Human Factor XIa is introduced from kit **lot#90J2909**, which was approved for release on February 28, 2012.

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This is to inform that a minor change has been made in the Rox Factor IX kit, Ref 900020 such that human Factor XIa has replaced bovine Factor XIa in Reagent B as activator of Factor IX.

This change has been made in recognition of the current development of different variants of rFIX, for which the characterization may benefit from using human enzyme species for activation.

**Importantly, the introduction of human Factor XIa as activator of Factor IX does not bring about any change in the kit method. Furthermore, all performance characteristics are maintained such as resolution, sensitivity and reagent stability.**

We sincerely hope this product change will have minimal impact on our customers. If you have any questions or need assistance please call +46 31 706 8965 or e-mail [info@rossix.com](mailto:info@rossix.com). We will respond promptly to any questions and/or comments in this matter.

Möln dal, March 01, 2012

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