Certificate of Analysis Factor XIa Control

REF Catalog number

1188

LOT

Batch code

HHW1934



Use by

2029 08



Upper limit of temperature

-20°C

Activity after reconstitution with 4.0 mL water:

Acceptance range 8.1 – 12.1 mIU/mL

The above Factor XIa activity apply only to Lot#HHW1934

The calibration was performed using the Rox Factor XIa kit (Ref#110050). Factor XIa Calibrator (Ref#1199), potency assigned vs the 1st International standard for Activated Blood Coagulation Factor XI (FXIa), Human, NIBSC code 13/100, was used as calibrator.

This Lot# has been approved for release after analyses according to established protocols with results demonstrating fulfillment of product specifications. All data concerning materials used, production data and release testing are documented and traceable under the individual Lot# which is stated on each package.

Pia Bryngelhed

Quality Manager, Rossix AB

September 5, 2024

Date



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