Rox Factor IX
Procedure for preparation of frozen aliquots of Reagent A and Reagent B and calibration with frozen reagents.

A  Reconstitution, pooling, aliquoting and freezing of Reagent A and Reagent B
1  Reconstitute a number of vials of Reagent A and Reagent B of the same lot number, respectively. Select the number based on an estimated analysis frequency. Allow each vial to reconstitute for 5 min at 20-25°C with intermittent gentle mixing for complete reconstitution.
2  Pool all vials of Reagent A in a plastic tube/beaker and pool all vials of Reagent B, in another plastic beaker. Mix gently.
3  For Reagent A, dispense 0.7 - 1.0 mL in plastic tubes. The volume should be selected for optimal use on the automated coagulation instrument.
4  For Reagent B, dispense 4 mL in plastic tubes. In case the laboratory might prefer to use a smaller volume for safer homogenous freezing, dispensing can be made of e.g. 2 mL per tube.
5  Freeze all aliquots at -70°C or colder. Make sure all tubes will be frozen homogenously by allowing a similar space between the tubes.

B  Calibration using frozen aliquots of reagents.
1. Thaw the number of tubes of Reagent A and B required for running at least two independent calibration curves. Perform thawing in a standardized way by placing the tubes in a water bath at 37°C for 5 minutes. After thawing, inverse the tubes gently a few times to ensure homogeneity. For optimal use of reagents, i.e. to minimize the impact of dead volumes, it may be practical to pool two or more tubes of Reagent A and of Reagent B, respectively.
2. Perform calibration in the high and low ranges according to the parameter listing for the automated instrument to be used. Use a normal reference plasma with assigned FIX activity in IU/mL traceable to a primary or secondary international plasma reference standard as calibrator.
3. Calculate the mean standard curve in the low and high ranges and store it in the instrument.

For any analysis of samples with frozen reagents, always adhere to the thawing procedure described in B1.
In each assay series, always include one or more controls as per the laboratorie’s routine procedure. Evaluate the samples and the control(s) vs the stored calibration curve.

In case Reagents A and B of the same lot numbers as used in A1, will be reconstituted at a later opportunity and handled according to A1, the same stored calibration curve can be used. This will hold only by strict adherence to the procedure in A1-A5.

When switching to a new lot of the Rox Factor IX kit, preparation of a new calibration curve is mandatory.

ROX FIX is for research use only in the U.S. and Canada

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