



technoclone



INR-Plasma Sets

Calibration and verification sets for INR-standardization according to the CLSI¹ und SSC² guidelines

¹ Clinical and Laboratory Standards Institute. Procedures for Validation of INR and Local Calibration of PT/INR Systems; Approved Guideline. CLSI document H54-A [ISBN 1-56238-580-1]; USA 2005

² Guidelines on the preparation, certification and use of certified plasmas for ISI calibration and INR determination, Journal of Thrombosis and Haemostasis, 2004, 2:1946-1653

A clear view into the future!

INR Plasma Sets

The AK-Calibrant and AK-Verification Kit contain plasmas for PT standardization. The lyophilized normal plasma pool is produced from selected plasmas of healthy donors. The AK-Plasmas are produced exclusively from plasma of donors receiving long-term oral anticoagulant therapy. Therefore the prothrombin complex factors II, VII, IX, X, Protein C and Protein S are present at levels normally expected in plasma from patients receiving oral anticoagulant treatment.

AK-CALIBRANT

The AK-Calibrant can be used for

- direct INR determination of a patients sample (INR reference curve),
- establishing laboratory, instrument and reagent specific ISI (International Sensitivity Index) and MNPT (Mean Normal Prothrombin Time) values and
- constructing a reference curve in percentage of the normal

The CLSI guideline states: "It is recommended that the certified plasma set consists of at least three abnormal plasma pools, and that one normal pooled plasma is used to define the calibration line. The three abnormal plasma pools should be chosen to cover the range of 1.5 to 4.5 INR."

According to that, the AK-Calibrant consists of:

AK-Calibrant A	lyophilized normal pooled plasma	
AK-Calibrant B	lyophilized AK-Plasma	INR ~ 2.0
AK-Calibrant C	lyophilized AK-Plasma	INR ~ 3.0
AK-Calibrant D	lyophilized AK-Plasma	INR ~ 4.0

AK-VERIFICATION KIT

The CLSI guideline states that "Verification of the local ISI using certified plasmas is always required following local system ISI calibration and prior to reporting patient results. This will ensure that adoption of the local ISI translates into accurate INR reporting. A minimum of three certified plasmas spanning the INR therapeutic range (1.5 to 4.5) are recommended for local system verification."

According to that, the AK-Verification Kit consists of:

Level 1	lyophilized AK-Plasma	INR ~ 2.0
Level 2	lyophilized AK-Plasma	INR ~ 3.0
Level 3	lyophilized AK-Plasma	INR ~ 4.0

Product	Description	REF	Package
AK-Calibrant	Calibrator Set of 4 calibrators (~ 1- 4 INR)	5010004	4 x 1 ml
AK-Verification Kit	Contains three plasmas with different INR values	5010024	3 x 1 ml

