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INTENDED PURPOSE
The Calibration Plasma set is intended for use with Thromboplastin LI for the following purposes:

- Establish a %PT Calibration Curve.
- Establish an INR Reference Curve for the direct INR determination of a patient sample.
- Establish specific ISI and MNPT values for the system, reagent and instrument, used by the laboratory.

WARNINGS AND PRECAUTIONS
The reagents contained within this kit are intended for in vitro diagnostic use only - **DO NOT INGEST**. Wear gloves when handling all kit components. Plasma products have been screened and found negative for the presence of Hepatitis B surface antigen (HbsAg), HIV 1 and 2 antibody and HCV antibody; however they should be regarded as potentially infectious and handled and disposed with appropriate care in compliance with local regulation.

COMPOSITION
The Calibration Plasma set contains 4 PT Calibrants for standardising the PT test. The plasmas are prepared from pooled normal human plasmas. PT Calibrant 1 simulates normal human plasmas, PT Calibrant 2, PT Calibrant 3 and PT Calibrant 4 simulate a range of plasma pathologies and are prepared through the absorption of clotting factors. The assigned values for each of the plasma are indicated on the insert sheet expressed as %PT and INR, the values are intended for use with Thromboplastin LI and are instrument/instrument series specific.

- 1 × 1 mL – PT Calibrant 1
- 1 × 1 mL – PT Calibrant 2
- 1 × 1 mL – PT Calibrant 3
- 1 × 1 mL – PT Calibrant 4

PREPARATION
Reconstitute with 1.0 mL of distilled or deionized water, allow the vial to stand for 15 minutes and mix gently before use to allow complete dissolution. **DO NOT SHAKE.**

STORAGE AND SHELF-LIFE
Unopened vials should be stored at 2-8°C and are stable until the expiration data stated on the labels. Reconstituted plasma must be used within 1 hour.

TEST PROCEDURE
The reconstituted plasmas should be treated in the same way as patient samples following normal instrument and thromboplastin protocols.

INTERPRETATION OF THE RESULTS

Establishing a %PT Calibration Curve
Determine the coagulation times of each of the 4 PT Calibrants in duplicate or triplicate. Plot the mean value obtained for each calibration plasma on double log paper (x-axis = %PT value; y-axis = Coagulation time in seconds). Join the points (point – point) and determine the PT coagulation time of the patient plasma and directly read from this reference line the corresponding %PT value of patient plasma.

Establishing an INR Reference Curve for the direct INR determination of a patient sample
Determine the coagulation times of each of the 4 PT Calibrants in duplicate or triplicate. Plot the mean value obtained for each calibration plasma on double log paper (x-axis = INR value; y-axis = Coagulation time in seconds). Join the points by fitting the best possible straight line through these points. Determine the PT coagulation time of the patient plasma and directly read from this reference line the corresponding INR value of patient plasma.

Establishing Laboratory Specific ISI and MNPT
Determine the coagulation times of each of the 4 PT Calibrants in duplicate or triplicate and calculate the mean value for each of the plasma. A linear relationship exists between the Log INR value (x-axis) and Log PT (sec; y-axis), expressed by the equation:

$$\text{Log PT (sec)} = [\text{slope} \times \text{Log (INR)}] + \text{intercept}$$

From this equation the laboratory specific ISI and MNPT can be calculated in the following way:

$$\text{ISI} = 1/\text{slope}$$
$$\text{MNPT} = 10^{\text{intercept}}$$

The PT Calibrants can be used on automated equipment. On Sysmex CA series and Sysmex CS series the assigned values of PT Calibrants can be entered as “Manual Dilution” in the “Standard Curve” sub-menu. Carefully read and follow the operating procedures for the specific instrument.

QUALITY CONTROL
Each laboratory should establish a quality control program. Normal and abnormal control plasmas should be tested prior to each batch of patient samples, to ensure satisfactory instrument and operator performance. If controls do not perform as expected, patient results should be considered invalid.
Helena BioSciences supply the following controls available for use with this product:

REF 5186 Routine Control N
REF 5187 Routine Control A
REF 5183 Routine Control SA
REF 5301 SAC N
REF 5302 SAC A

REFERENCE VALUES
Reference values can vary between laboratories depending on the techniques and systems in use.

LIMITATION OF THE TEST
A new calibration is required for each batch of thromboplastin and for each instrument used. Recalibration is also recommended if software changes are introduced or following a major service or repair of the instrument.

The INR and %PT values of calibration plasmas supplied with this kit are lot specific.

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Calibration Plasma
Instructions for use

REF 5504R

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HL-2-2658P 2012/11 (1)

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