PT Calibrator Set

REF SC084K-RUO

CAL1 | CAL2 | CAL3 | CAL4 | CAL5

2 vials x 1 mL

FOR RESEARCH USE ONLY.
DO NOT USE IN DIAGNOSTIC PROCEDURES.

HYPHEN BioMed
155 rue d'Eragny, 95000 Neuville-sur-Oise, France
Tél : +33 (0)1 34 40 65 10
Fax : +33 (0)1 34 48 72 36
www.hyphen-biomed.com
info@hyphen-biomed.com

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INTENDED USE:

PT Calibrator set is a set of five certified plasmas for PT/INR and PT% calibration and/or for verification of local ISI test system.
This device of *in vitro* use is intended for professional use in the laboratory.
This kit is for research use only and must not be used for patient diagnosis or treatment.

SUMMARY AND EXPLANATION:

Technical: [1]
These calibrators are used to establish the calibration curve for PT clotting assays in human plasma ((h)PT-Phen™ and PT-Phen™ LRT).
The various INR values are obtained by mixing a normal plasma pool and normal plasma partially depleted in different factors of prothrombin complex. INR (International Normalized Ratio) is defined as:

$$INR = \left[\frac{PT(sec)\ plasma}{MNPT} \right]^{ISI}$$

REAGENTS:

CAL1 Lyophilized human plasma with INR value at approximately 1.0.
CAL2 Lyophilized human plasma with INR value at approximately 2.0.
CAL3 Lyophilized human plasma with INR value at approximately 3.0.
CAL4 Lyophilized human plasma with INR value at approximately 4.0.
CAL5 Lyophilized human plasma with INR value at approximately 5.0.

Calibrator plasmas contain stabilizing agents.

The assigned values (INR, PT%) may vary slightly from one batch to another. For the assay, see the exact values indicated on the flyer provided with the kit used.

The product is classified as non-hazardous and is not subject to labeling according to EC Regulation No. 1272/2008 [CLP].

WARNINGS AND PRECAUTIONS:

- Some reagents provided in these kits contain materials of human origin. Whenever human plasma is required for the preparation of these reagents, approved methods are used to test the plasma for the antibodies to HIV 1, HIV 2 and HCV, and for hepatitis B surface antigen, and results are found to be negative. However, no test method can offer complete assurance that infectious agents are absent. Therefore, users of reagents of these types must exercise extreme care in full compliance with safety precautions in the manipulation of these biological materials as if they were infectious.
- Waste should be disposed of in accordance with applicable local regulations.

REAGENT PREPARATION:

Gently remove the freeze-drying stopper, to avoid any product loss when opening the vial.

CAL1 **CAL2** **CAL3** **CAL4** **CAL5** Reconstitute the contents of each vial with exactly **1 mL of distilled water.**
Shake vigorously until complete dissolution while avoiding formation of foam and load it directly on the analyzer following application guide instruction.

This plasmatic reagent can be more or less turbid after reconstitution. This turbidity is mainly due to plasma lipids that, after freeze-drying, become "less" soluble and may form a slight deposit. If necessary, let each vial stabilize 10 minutes at room temperature and shake before use.

STORAGE AND STABILITY:

Unopened reagents should be stored at 2-8°C in their original packaging. Under these conditions, they can be used until the expiry date printed on the kit.

CAL1 **CAL2** **CAL3** **CAL4** **CAL5** Reagent stability after reconstitution, free from any contamination or evaporation, and stored closed, is of:

- **24 hours** at 2-8°C.
- **Stability on board of the analyzer: see the specific Application Guide.**

REAGENTS AND MATERIALS REQUIRED BUT NOT PROVIDED:

- Laboratory material

TRACEABILITY:

The INR value assignment of calibrators is determined according to H54-A guideline[1] by HYPHEN BioMed and/or external validation laboratory.
Certificate of traceability and uncertainty is available on request.

QUALITY CONTROL:

For calibration of PT assays by clotting method, provided by (h)PT-Phen™ (CK581-RUO/CK582-RUO/CK583-RUO) and PT-Phen™ LRT (CK584K-RUO/CK584L-RUO/CK586K-RUO/CK586L-RUO) kits.
The target values are determined from multi-reagent and multi-instrument tests.
The use of quality controls serves to validate method compliance, along with between-series assay homogeneity for a given batch of reagents.
Include the quality controls with each series, as per good laboratory practice, in order to validate the test.
A new calibration curve should be established:

- preferably for each test series **but at least every 3 months,**
- for each new reagent batch,
- after analyzer maintenance,
- when the measured quality control values fall outside the acceptance range for the method.

Direct determination of patient INR or PT% value[1]
Realize an INR (or PT%) reference calibration curve by determining the clotting times of PT Calibrator Set (SC084K-RUO) and plotting log-log on abscissae the INR (or PT%) values and on ordinates the corresponding clotting times (seconds). The INR (or PT%) value of tested plasma is directly obtained on the calibration curve.
This method is independent of International Sensitivity Index (ISI) and MNPT values.

LIMITATIONS:

- If the calibrators are used under measurement conditions other than those validated by HYPHEN BioMed, the test results may vary. The laboratory is responsible for validating the use of these calibrators in its own analytical system.
- Any reagent presenting no limpid appearance or showing signs of contamination must be rejected.
- A new calibration curve is necessary for each batch of PT reagent and for each instrument used, as well as MNPT as needed.

The results obtained should be for research use only and must not be used for patient diagnosis or treatment.

REFERENCES:

1. Clinical and Laboratory Standards Institute; Procedures for validation of INR and Local Calibration of PT/INR Systems; H54-A, Vol.25, number 23.
2. Clinical and Laboratory Standards Institute (CLSI). One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test; Approved Guideline - Second Edition CLSI document H47-A2, Vol. 28 No. 20. 2008.
3. Poller L. et al. The prothrombin time/international normalized ratio (PT/INR) Line: derivation of local INR with commercial thromboplastins and coagulometers – two independent studies. J. Thromb Haemost. 2011.

Changes compared to the previous version.

REF	Catalog number	LOT	Batch code	RUO	Product for *in-vitro* research use, only
WHO STD	WHO standard code		See instructions for use	→	Reconstitution volume
YYYY-MM-DD	Use by		Manufacturer	Cx	Numerical < x> identification of control
CONTENTS	Contents	UNIT	Measurement unit		Temperature limitation
TARGET VALUE	Target Value			ACCEPTANCE RANGE	Acceptance range
CONTAINS	Contains	EXP	Expiration date	i- MA	See instructions in Method Application guide