

Application Sheet for Prothrombin Time (PT-SI) with HEMOSTAT Thromboplastin-SI

HumaClot Pro **REF** 15800

For additional information, please refer to the respective User Manual of the instrument and check current instructions for use for reagents, controls, calibrators and tables of assigned/analytical values. Typical performance data can be found in the Verification Report of the instrument, accessible via

www.human.de/data/gb/vr/15800.pdf
www.human-de.com/data/gb/vr/15800.pdf

If the performance data are not accessible via internet, they can be obtained free of charge from your local distributor.

The parameters defined in this application sheet have been developed to provide optimal product performance with the assay and instrument combination. Any modification to these parameters may affect performance of this and other assays in use on your system and the resulting assay values. It is the responsibility of the user to validate any modifications and their impact on all assay results. The application sheet lists all combinations of controls and calibrators for use with the reagent and instrument system; other combinations are not validated or supported.

Materials Required

Material	REF	Size	On-Board Position
HEMOSTAT Thromboplastin-SI			
RG Thromboplastin reagent	31002	6 x 2 ml	R1-R3 with magnetic stirrer and reducer ring
BU Reconstitution medium		6 x 2 ml	for reconstitution of RG only
HEMOSTAT Thromboplastin-SI			
RG Thromboplastin reagent	31003	6 x 10 ml	R1-R3 with magnetic stirrer
BU Reconstitution medium		6 x 10 ml	for reconstitution of RG only
CA HEMOSTAT Calibrator	35500	4 x 1 ml	C1 in sample cup for calibration
NaCl 0.9% Sodium Chloride	-	2 ml	C2 in cup, for dilution of calibrator
CPN HEMOSTAT Control Plasma Normal	35001	6 x 1 ml	Sample rack position 01-22 or Position C5-C6 (when using QC-program)
CPA HEMOSTAT Control Plasma Abnormal	35002	6 x 1 ml	
Cuvette Ring	15800/10	6 x 10 x 32 pcs	Cuvette Ring Rotor
WASH HumaCLOT Pro Wash Solution	15800/20	15 ml	W1
CLEAN HumaCLOT Pro Cleaner	15800/30	15 ml	W2
Sample Cups (2 x 250 pcs) "Human" or Sample Cups (500 pcs) "Hitachi"	15800/25	4 ml	-
	17470/59	2 ml	-
Reducer Ring (3 pcs)	15800/536		R1 – R3
Empty vials (50 x 5 ml)	15800/40	-	optional
Magnetic stirrer (10 pcs) (to be cleaned with Wash Solution; REF 15800/20)	15800/50		

Additional Notes

The required controls have to be transferred into appropriate sample cups.

On-Board Stability

Material	Name in the Test Protocol	Listed in the Test Setting as	Time [h]
[RGT] HEMOSTAT Thromboplastin Reagent	PT-SI RGT	Start-Reagent	72 (10 ml) 32 (2 ml)
[CPN] HEMOSTAT Control Plasma Normal	-	Load as sample or as QC (when using QC-program)	4
[CPA] HEMOSTAT Control Plasma Abnormal	-	Load as sample or as QC (when using QC-program)	4
[CAL] HEMOSTAT Calibrator	-	Load as calibrator	2

The stated stability data were established under controlled laboratory conditions. The above-mentioned on-board stability values may deviate due to differences in laboratory environmental conditions.

Reagent Settings

Enter the LOT numbers into the reagent settings.

Reagent Setup		
[REF]	31002	31003
HEMOSTAT Test	HEMOSTAT Thromboplastin-SI	HEMOSTAT Thromboplastin-SI
Test Setup: Reagent name	Hemostat PT-SI	Hemostat PT-SI
Reagent name	PT SI RGT	PT SI RGT
Position in the list	1	1
Abbreviation	PT-SI	PT-SI
LOT	<i>Please insert LOT-number</i>	<i>Please insert LOT-number</i>
Vial	5ml-HumGL*	15ml-HumGL**

*5ml-HumGL (5ml HUMAN Glass Bottle)

**15ml-HumPL (15ml HUMAN Glass Bottle)

Interference Studies

PT-SI setting 405nm (default "Hemostat PT-SI", short "PT-SI")

No interference up to ...					
Bilirubin	mg/dl	25	spiked normal plasma	25	spiked pathological plasma
Hemoglobin	mg/dl	357	spiked normal plasma	139	spiked pathological plasma
Lipids	mg/dl	750	spiked normal plasma	349	spiked pathological plasma

When interfering substances cause very high absorption of light a "F" Flag might be displayed as state. This raw value error indicates that the photometer cannot detect proper clotting within the noise of the signal. The optional PT-SI setting 570nm may be applied in these cases – it shows a lower sensitivity towards interfering substances.

PT-SI setting 570nm ("Hemos PT-SI 570", short "PTS15");

recommended for samples with higher levels of bilirubin, hemoglobin and lipids)

No interference up to ...					
Bilirubin	mg/dl	50	spiked normal plasma	50	spiked pathological plasma
Hemoglobin	mg/dl	500	spiked normal plasma	1000	spiked pathological plasma
Lipids	mg/dl	1000	spiked normal plasma	349	spiked pathological plasma

Performance Characteristics

Measuring Range	
Valid Clotting	9 - 80 s

Reference Interval

The following data was obtained with a specific HEMOSTAT Thromboplastin-SI lot using normal plasma according to EP28-A3.

HumaClot Pro	Median	95% Reference interval	
		2.5th Percentile	97.5th Percentile
169 samples	11.9 s	10.6 s	13.6 s
169 samples	101 %	74.7 %	131 %
169 samples	1.00 INR	0.87 INR	1.17 INR

Please note: reference intervals vary from laboratory to laboratory depending on the population served, technique and reagent lot used. Therefore, each laboratory must establish its own reference intervals or verify them whenever one or more of the mentioned variables are changed.

For more information how to establish reference intervals see CLSI document C28-A3.

Calibration Setting

A new standard curve must be established when changing a kit LOT, after major maintenance or service, if indicated by quality control results and when required by laboratory control procedures and/or government regulations.

Test Hemostat PT-SI	
Field Name	Settings
1 st conversion	Interpolation
Unit conversion	s -> %
Mode: in/out	log -> log
Output Format	xxx.xx
2 nd conversion	INR
MNPT***	<i>MNPT-value appears automatically after calibration (sec)</i>
ISI**	<u>Please insert ISI</u>
Auto-Calibration	
Diluent	NaCl
Determination	1
Cup	Human/ Hitachi
Calibration Values	
0	90 %
1	50 %
2	25 %
3	12.5 %
4	0.0 %
Standard	
Concentration	<u>Please insert concentration (%)*</u>
Name	Hemostat Cal
LOT	<u>Please insert LOT Number</u>
Conversion range	5 % - 150 %

* The LOT-specific calibration value can be found on the table of analytical values in the calibration kit.

**The LOT specific ISI value can be found on the table ISI values of the Thromboplastin reagent kit.

Please note:

1st conversion (→ %) and 2nd conversion (→ INR) are optional and can be switched off by entering “none” into the corresponding field.

If only the 1st conversion (→ %) is switched off, it is required to enter the MNPT*** value manually. For further information please refer to the User Manual.

