Application Sheet for Prothrombin Time (PT) 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.

Material Required

Material	REF	Size	On-Board Position
Hemostat Thromboplastin-SI	31002		
RGT **Thromboplastin reagent**		6 x 2 ml	R1-R3 with magnetic stirrer and reducer ring
BUF **Reconstitution medium**		6 x 2 ml	for reconstitution of RGT only
Hemostat Thromboplastin-SI	31003		
RGT **Thromboplastin reagent**		6 x 10 ml	R1-R3 with magnetic stirrer
BUF **Reconstitution medium**		6 x 10 ml	for reconstitution of RGT only
CAL **Calibrator**	35500	4 x 1 ml	C1 in cup
CPN **Hemostat Control Plasma Normal**	35001	6 x 1 ml	Sample rack position 01-22 or Position C3-C8 (when using QC-program)
CPA **Hemostat Control Plasma Abnormal**	35002	6 x 1 ml	
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 17470/59	4 ml 2 ml	- -
Reducer Ring (3 pcs)	15800/536		R1 – R3
Magnetic stirrer (10 pcs) **(to be cleaned with Wash Solution;** **REF 15800/20)**	15800/50		
Sodium Chloride (NaCl 0.9%)	-	2 ml	C2 in cup, for dilutions

On-Board Stability

Material	Name in the Test Protocol	Listed in the Test Setting as	Time [h]
RGT Thromboplastin reagent	PT-SI RGT	Start-Reag	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	6

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.

Measuring Range	
Valid Clotting	9-80 sec

Reference Interval			
n=25			
Mean	13.3 sec	**Median**	13.5 sec
-2SD	11.1 sec	**5th Percentile**	11.4 sec
+2SD	15.5 sec	**95th Percentile**	14.7 sec

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 on how to establish reference intervals see CLSI document C28-A3.

Enter the LOT numbers into the reagent settings.

Reagent Settings

Screen Edit Reagent		
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	*Please insert LOT-number*	*Please insert LOT-number*
Vial	5ml-HumGL*	15ml-HumGL*

*5ml-HumGL (5ml HUMAN Glass Bottle), 15ml-HumGL (15ml HUMAN Glass Bottle)

Standard Curve Calibration

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.

Standard Curve Calibration

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

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

Please note:
1nd conversion (→ %) and 2rd 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.

Performance Characteristics

Method Comparison		
Predicate Device	**Regression Equation**	**r**
PT REC- on STA-R Evolution	1.079x-0.2109	0.875

Precision				
		within run CV (%)	**run to run CV (%)**	**total CV (%)**
BioRad Lyphocheck Coagulation Control	Level 1	0.98	0.56	0.94
	Level 2	1.74	1.38	1.46
	Level 3	1.77	1.23	1.58

CE