Application Sheet for Thrombin Time with Hemostat Thrombin Time (REF 34002)

HumaClot Junior (model HC1) REF **18680**
HumaClot Duo Plus (model HC2) REF **15650**
HumaClot Quattro (model HC4) REF **15660**

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/18680.pdf
www.human-de.com/data/gb/vr/18680.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 Thrombin Time	34002		
RGT **Thrombin reagent**		2 ml	beside the analyzer
CPN **Hemostat Control Plasma Normal**	35001	6 x 1 ml	-
Cuvettes with pre-filled mixers	15660/10	5 x 100 pcs	-
Cuvette bag with separate mixer	15660/11	500 pcs	-
Cuvette bag with separate mixer	15660/12	5 x 500 pcs	-

Additional Notes

If reagents, rinse solutions or buffers are not supplied in exactly fitting vials it is necessary to transfer them into appropriate vials. The required controls have to be transferred into appropriate sample cups.

On-Board Stability

Material	Time [h]
Hemostat Thrombin Time	
RGT **Thrombin Reagent at RT**	24
CPN **Hemostat Control Plasma Normal**	4

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.

Interference Studies

No Interference up to			
Triglycerides	mg/dl	250	Spiked normal plasma
Hemoglobin	mg/dl	200	Spiked normal plasma
Bilirubin	mg/dl	30	Spiked normal plasma

Measuring Range	
Valid Clotting for Test TT ext	10.1-300 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 how to establish reference intervals see CLSI document C28-A3.

Pipetting Scheme

Pipetting	
Pre-warm RGT at RT and sample test cups at 37°C	
1.Pre-dilute sample	75 µl
Transfer measuring cup with sample to a measuring position	
Incubation time	60 s
2.Start reagent RGT (Hemostat TT)	75 µl
Autostart	yes

Reagent Settings

Test Hemostat TT	
(Full Setup, User) <TT>+Enter-Key=CuvIN or Pat-ID+0-key	
Method Store	4
'Thrombin T'	
Date	Will be displayed
Measuring Time	301 s
Gain_idx	0
Cuv in	ON
Reg_sens	ON
Start Reagent	
LOT	Please insert LOT number
Volume	75 µl
incu	60 s
Clotting	ON
1st convers	NONE
2nd convers	NONE

Calibration Settings

Hemostat TT is a non-calibrated test.

Performance Characteristics

Method comparison			
Test Device	**Predicate Device**	**Regression Equation**	**r**
Hemostat TT / Junior	Hemostat TT /HC Pro	y=0.9434x+0.4116	0.9820
Hemostat TT / Duo Plus		y=0.9613x+1.0391	0.9853
Hemostat TT/ Quattro		y=0.9349x+0.9561	0.9915

Precision				
		Within Run CV (%)	Run to Run CV (%)	Total CV (%)
HumaClot Junior				
BioRad Lyphocheck Coagulation Control	Level 1	Max: 1.33	0.89	1.08
HumaClot Duo Plus				
BioRad Lyphocheck Coagulation Control	Level 1	Max: 1.79	1.20	1.38
HumaClot Quattro				
BioRad Lyphocheck Coagulation Control	Level 1	Max: 1.69	1.40	1.68

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