

Application Sheet for Activated Partial Thromboplastin Time (aPTT) with HEMOSTAT aPTT-EL

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 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 aPTT-EL	33002	6 + 6 x 4 ml	
RGT1 aPTT-EL		6 x 4 ml	Beside the analyzer
RGT2 CaCl ₂		6 x 4 ml	Heated Reagent position
HEMOSTAT aPTT-EL	33012		
RGT1 aPTT-EL		6 x 4 ml	Beside the analyzer
RGT2 CaCl ₂		4 x 30 ml	Heated Reagent position
HEMOSTAT aPTT-EL	33013		
RGT1 aPTT-EL		6 x 10 ml	Beside the analyzer
RGT2 CaCl ₂		4 x 30 ml	Heated Reagent position
CPN HEMOSTAT Control Plasma Normal	35001	6 x 1 ml	-
CPA HEMOSTAT Control Plasma Abnormal	35002	6 x 1 ml	
Cuvettes with pre-filled mixers	15660/10	5 x 100 pcs	-
Cuvettes bag with separate mixers	15660/11	500 pcs	
Cuvettes bag with separate mixers	15660/12	5 x 500 pcs	
Reducer Ring	15660/52	2pcs	Standard accessory HumaCLOT Duo Plus/ Quattro
Empty vials (50 x 5ml)	15800/40	-	If required for CaCl ₂

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]
[RGT1] aPTT-EL	72
[RGT2] CaCl ₂	30
[CPN] HEMOSTAT Control Plasma Normal	4
[CPA] HEMOSTAT Control Plasma Abnormal	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.

Pipetting Scheme

Pipetting Scheme	
<i>Pre-warm [RGT2] (CaCl₂) and cuvettes at 37°C</i>	
1. Sample	50 µl
2. Hemostat aPTT-EL [RGT1] (aPTT-EL)	50 µl
<i>Transfer cuvette with sample and [RGT1] into the measuring channel</i>	
Incubation time	120 s
3. Start reagent [RGT2]	50 µl
Autostart	Yes*

*Autostart can be influenced by hemoglobin, bilirubin and triglycerides (HIL). If the autostart function is not initiated due to elevated levels of HIL it is recommended to collect new blood samples from the patient. If this is not applicable, or the autostart function still is not initiating it is possible to start the measurement manually by pressing the respective channel button.

Please note: a manual start may lead to slightly shorter or prolonged and less accurate aPTT values. Therefore, each result of an HIL-sample should be reported with restrictions and marked with notes.

Reagent Settings

Test Protocol _Printed automatically with every change / new start	
<i>(Reduced Setup, User) <aPTT>+Enter-Key=CuvIN or Pat-ID+0-key</i>	
Method Store	2
'aPTT'	
Date	Will be displayed
Measuring Time	241 s
Gain_idx	0
Cuv in	On
Reag_sens	Off
Start Reagent	
LOT	Please insert LOT
Volume	50 µl
incu	120 s
Clotting	ON
1 st convers	NONE
2 nd convers*	RATIO
MNP*	28.0 s

*if 2nd RATIO it is required please establish and enter the LOT-specific the mean normal aPTT value into "MNP"

Calibration settings

Hemostat aPTT-EL is a non-calibrated test.

Interference Studies

no interference up to			
Bilirubin	mg/dl	40	Spiked normal plasma
Hemoglobin	mg/dl	580	Spiked normal plasma
Lipids	mg/dl	1000	Spiked normal plasma

Measurement

Measuring Range	
Valid Clotting	20 - 240 s

Reference Interval
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.

