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, 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 aPTT-EL	33002 33012 33013 33022	6 x 4 ml	
RGT1 **aPTT-EL**		4 ml	Beside the analyzer
RGT2 **CaCl2**		4 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 dispo incl. mixer	15660/10	5 x 100 pcs	-
Cuvettes bag incl. mixer	15660/11	500 pcs	
Cuvettes bag incl. mixer	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 CaCl2

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 **CaCl2**	30
Hemostat Control Plasma Normal	4
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.

Interference Studies

no interference up to			
Bilirubin	mg/dl	50	Spiked normal plasma
Hemoglobin	mg/dl	1000	Spiked normal plasma
Lipids	mg/dl	700	Spiked normal plasma
Triglycerides	mg/dl	3500	Spiked normal plasma

Measuring Range	
Valid Clotting	20-240 sec

Reference Interval			
n=51			
Mean	28 sec	**Median**	28.3 sec
-2SD	21.6 sec	**5th Percentile**	21.5 sec
+2SD	34.4 sec	**95th Percentile**	32.65 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	
Pre-warm RGT2 (CaCl2) and cuvettes at 37°C	
1.Sample	50 µl
2.Hemostat aPTT RGT1 (aPTT-EL)	50 µl
Transfer cuvette with sample and RGT1 into the measuring channel	
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 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 Hemostat PT-SI	
(Full Setup, User) <PT>+Enter-Key=CuvIN or Pat-ID+0-key	
Method Store	2
'aPTT'	
Date	Will be displayed
Measuring Time	241 s
Gain_idx	0

Cuv in	On
Reg_sens	Off
Start Reagent	
LOT	Please insert LOT
Volume	50 µl
incu	120 s
Clotting	ON
1st convers	NONE
2nd convers*	RATIO
MNPT	28.0 s

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

Calibration settings

Hemostat aPTT-EL is a non-calibrated test.

Performance Characteristics

The following studies were conducted using specimens collected in 3.2 % sodium citrate solution.

Method Comparison			
Test device	**Predicate Device**	**Regression Equation**	**r**
Hemostat APTT / Junior	Hemostat APTT /HC Pro	y=0.9926x-0.1579	0.9838
Hemostat APTT / Duo Plus		y=0.9930x-1.4488	0.9878
Hemostat APTT / Quattro		y=0.9959x-1.8154	0.9872

Precision				
		Within Run CV (%)	**Run to Run CV (%)**	**Total CV (%)**
HumaCLOT Junior				
BioRad Lyphocheck Coagulation Control	Level 1	Max: 1.97	1.10	1.64
	Level 3	Max: 4.93	3.19	4.50
HumaCLOT Duo Plus				
BioRad Lyphocheck Coagulation Control	Level 1	Max: 1.64	1.26	1.44
	Level 3	Max: 3.47	2.41	2.54
HumaCLOT Quattro				
BioRad Lyphocheck Coagulation Control	Level 1	Max: 1.87	1.39	1.39
	Level 3	Max: 1.82	0.81	1.97

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