

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 **REF 15660**

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 the 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.

For additional information, please refer to the respective User Manual of the instrument and check current instructions for use (IFU) for reagents, controls and tables of assigned values.

Typical performance data can be found in the Verification Report of the respective instrument, accessible via

www.human.de/data/gb/vr/18680.pdf

www.human.de/data/gb/vr/15650.pdf

www.human.de/data/gb/vr/15660.pdf

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

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			
[RGT1] aPTT-EL	33012	6 x 4 ml	Beside the analyzer
[RGT2] CaCl ₂	33022	4 x 30 ml	Heated reagent position
HEMOSTAT aPTT-EL			
[RGT1] aPTT-EL	33013	6 x 10 ml	Beside the analyzer
[RGT2] CaCl ₂	33022	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	Pre-heated cuvette positions
Cuvettes bag with separate mixers	15660/11	500 pcs	
Cuvettes bag with separate mixers	15660/12	5 x 500 pcs	
Reducer Ring	15660/52	2 pcs	Standard accessory HumaClot Duo Plus/ Quattro
Reagent container	15800/40	50 x 5 ml	If required for [RGT2] CaCl ₂

Additional Notes

If [REF] 33022 is used as [RGT2] it is necessary to transfer the required volume into appropriate vials [REF] 15800/40. Discard remaining [RGT2] at the end of the day.

Pipetting Scheme

Pipetting Scheme	
Pre-warm [RGT2] CaCl ₂ and cuvettes at 37°C	
1. Sample	50 µl
2. [RGT1] aPTT-EL	50 µl
Transfer cuvette with sample and [RGT1] into the measuring channel	
Incubation time	120 s
3. Start reagent [RGT2] CaCl₂	50 µl
Auto start*	Yes

*Auto start can be influenced by hemoglobin, bilirubin and triglycerides (HIL). If the auto start 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 auto start 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.

Calibration settings

HEMOSTAT aPTT-EL is a non-calibrated test.

Test Settings

Test Protocol _Printed automatically with every change / new start	
<i>(Reduced Setup, User) <2> +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 number
Volume	50 µl
incubation	120 s
Clotting	ON
1 st conversion	NONE
2 nd conversion	RATIO
MNP	Please insert MNP

Please note:

If the second conversion RATIO is required, please establish and enter the LOT-specific mean normal aPTT value into "MNP". For further information how to set MNP value please refer to the User Manual.

On-Board Stability

Material	Time [h]
RGT1 aPTT-EL	72
RGT2 CaCl ₂	30

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	50	spiked pathological plasma
Hemoglobin	mg/dl	580	spiked normal plasma	640	spiked pathological plasma
Lipids	mg/dl	1000	spiked normal plasma	1000	spiked pathological plasma

Performance Characteristics

Measuring interval	
Valid Clotting	20 - 240 s

Reference Interval			
The following data was obtained with a specific HEMOSTAT aPTT-EL LOT using normal plasma according to EP28-A3.			
HumaClot Quattro	Median	95% Reference interval	
		2.5th Percentile	97.5th Percentile
167 samples	25.0 s	21.7 s	31.1 s
<p><i>Please note: The 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.</i></p> <p>For more information how to establish reference intervals see CLSI document C28-A3.</p>			

