

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

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 and tables of assigned 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 for use with the reagent and instrument system; other combinations are not validated or supported.

Materials Required

Material	REF	Size	On-board position
HEMOSTAT aPTT-EL		6 + 6 x 4 ml	
RGT1 aPTT-EL	33002	6 x 4 ml	R4 - R15
RGT2 CaCl ₂		6 x 4 ml	R4 - R15
HEMOSTAT aPTT-EL			
RGT1 aPTT-EL	33012	6 x 4 ml	R4 - R15
RGT2 CaCl ₂	33022	4 x 30 ml	R4 - R15
HEMOSTAT aPTT-EL			
RGT1 aPTT-EL	33013	6 x 10 ml	R1 - R3; change position manually from R4 - R15 to R1 - R3
RGT2 CaCl ₂	33022	4 x 30 ml	R4 - R15
CPN HEMOSTAT Control Plasma Normal	35001	6 x 1 ml	Sample rack position 01 - 22 or Position C5 – C6 (when using QC-program)
CPA HEMOSTAT Control Plasma Abnormal	35002	6 x 1 ml	
Cuvette Ring	15800/10	6 x 10 x 32 pcs	Cuvette Ring Rotor
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"	15800/25	4 ml	-
or Sample Cups (500 pcs) "Hitachi"	17470/59	2 ml	-
Empty vials (50 x 5 ml)	15800/40	-	Required if REF 33022 is used as RGT2

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. The required controls have to be transferred into appropriate sample cups.

On-Board Stability

Material	Name in Test Protocol	Listed in the Test Setting as	Time [h]
[RGT1] aPTT-EL	aPTT RGT 1	Reagent 2	72
[RGT2] CaCl ₂	CaCl ₂ RGT 2	Start-Reagent	32
[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

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.

Reagent Settings

Enter the LOT numbers into the reagent settings.

Reagent Setup			
[REF]	33002; 33012	33013	33002; 33022
HEMOSTAT Test	Hemostat aPTT-EL	Hemostat aPTT-EL	Hemostat aPTT-EL
Reagent Name	aPTT RGT 1	aPTT RGT 1	CaCl ₂ RGT2
Position in List	2	2	3
Abbreviation	aPTT	aPTT	CaCl ₂
LOT	<i>Please insert LOT-number</i>	<i>Please insert LOT-number</i>	<i>Please insert LOT-number</i>
Vial	5ml-HumGL*	15ml-HumGL**	5ml-HumPL***

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

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

*** 5ml-HumPL (5ml HUMAN Plastic Bottle)

Interference Studies

aPTT setting 405nm (default test "Hemostat aPTT", short "aPTT")

No interference up to ...					
Bilirubin	mg/dl	21	spiked normal plasma	30	spiked pathological plasma
Hemoglobin	mg/dl	200	spiked normal plasma	200	spiked pathological plasma
Lipids	mg/dl	600	spiked normal plasma	300	spiked pathological plasma

When interfering substances cause very high absorption of light a "F" Flag might be displayed as state. This raw value error indicates that the photometer cannot detect proper clotting within the noise of the signal. The optional aPTT setting 570nm may be applied in these cases – it shows a lower sensitivity towards interfering substances.

aPTT setting 570nm ("Hemos aPTT 570", short "aPTT5");

recommended for samples with higher levels of bilirubin, hemoglobin and lipids)

No interference up to ...					
Bilirubin	mg/dl	23	spiked normal plasma	48	spiked pathological plasma
Hemoglobin	mg/dl	1000	spiked normal plasma	728	spiked pathological plasma
Lipids	mg/dl	600	spiked normal plasma	800	spiked pathological plasma

Performance Characteristics

Measuring Range	
Valid Clotting	20 - 180 s

Reference Interval			
The following data was obtained with a specific HEMOSTAT aPTT-EL lot using normal plasma according to EP28-A3c			
HumaClot Pro	Median (seconds)	95 % Reference interval (seconds)	
		2.5th Percentile	97.5th Percentile
166 samples	26.1	22.5	32.4
Please note: 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.			

Calibration Settings

Hemostat aPTT-EL is a non-calibrated test.

