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, 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/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 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 x 4 ml	
RGT1 **aPTT-EL**		4 ml	R1-R3 with magnetic stirrer and reducer ring
RGT2 **CaCl2**		4 ml	R4-R15
CPN **Hemostat Control Plasma Normal**	35001	6 x 1 ml	Sample rack position 01-22 or Position C3-C8 (when using QC-program)
CPA **Hemostat Control Plasma Abnormal**	35002	6 x 1 ml	
WASH **HumaCLOT Pro Washing Solution**	15800/20	15 ml	W1
CLEAN **HumaCLOT Pro Cleaner**	15800/30	15 ml	W2
Sample Cups (2 x 250 pcs) Human" **or Sample Cups (500 pcs) "Hitachi"**	15800/25 17470/59	4 ml 2 ml	- -
Reducer Ring (3 pcs)	15800/536		R1 – R3
Magnetic stirrer (10 pcs) **(to be cleaned with Wash Solution; REF 15800/20)**	15800/50		
Empty vials (50 x 5 ml)	15800/40	-	If required for dilutions

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	Name in Test Protocol	Listed in the Test Setting as	Time [h]
RGT1 **aPTT-EL**	aPTT RGT 1	Reagent 2	72
RGT2 **CaCl2**	CaCl2 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.

Measuring Range	
Valid Clotting	20-180 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.

Enter the LOT numbers into the reagent settings.

Reagent Settings

Screen Edit Reagent		
REF	**33002**	
Hemostat Test	Hemostat aPTT-EL	Hemostat aPTT-EL
Reagent Name	aPTT (RGT 1)	CaCl2 (RGT 2)
Position in List	2	3
Abbreviation	aPTT	CaCl2
LOT	Please insert Lot number	Please insert Lot number
Vial	5ml-HumGL*	5ml-HumPL*
Stirring Parameter: Cycle time	60 s	-
Stirring Parameter: Cycle pause	45 s	-
Aspiration	slow	slow
Dispension	high	high
Washing	normal	normal
Stability (h)	72	32
Waste volume (µl)	5	5
Calibrate	no	no

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

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		
Predicate Device	**Regression Equation**	**r**
Stago APTT on STA-R Evolution	1.000x-1.3500	0.961

Precision				
		within run CV (%)	**run to run CV (%)**	**total CV (%)**
BioRad Lyphocheck Coagulation Control	Level 1	0.59	0.48	0.53
	Level 2	0.59	0.49	0.51
	Level 3	1.18	0.87	0.93

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