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/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 + 6 x 4 ml	
RGT1 aPTT-EL		6 x 4 ml	R1 - R3 with magnetic stirrer and reducer ring
RGT2 $CaCl_2$		6 x 4 ml	R4 - R15
HEMOSTAT aPTT-EL	33012 / 33022		
RGT1 aPTT-EL	33012	6 x 4 ml	R1 - R3 with magnetic stirrer and reducer ring
RGT2 $CaCl_2$	33022	4 x 30 ml	R4 - R15
HEMOSTAT aPTT-EL	33013 / 33022	6 + 6 x 4 ml	
RGT1 aPTT-EL	33013	6 x 10 ml	R1 - R3 with magnetic stirrer
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 C3 - C8 (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 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	-	Required if REF 33022 is used as RGT2

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 **$CaCl_2$**	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.

Reagent Settings

Enter the LOT numbers into the reagent settings.

Screen Edit Reagent			
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	CaCl2 RGT2
Position in List	2	2	3
Abbreviation	aPTT	aPTT	CaCl2
LOT	*Please insert LOT-number*	*Please insert LOT-number*	*Please insert LOT-number*
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

No interference up to ...			
Bilirubin	mg/dl	30	spiked normal and pathological plasma
Hemoglobin	mg/dl	140	spiked normal and pathological plasma
Lipids	mg/dl	500	spiked normal and pathological plasma

Performance Characteristics

Measuring Range	
Valid Clotting	20 - 180 sec

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.

Calibration Settings

Hemostat aPTT-EL is a non-calibrated test.

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