

Application Sheet for Antithrombin with Hemostat Antithrombin liquid (REF 36102)

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 Antithrombin liquid	32002		
RG1 Antithrombin Reagent		4 x 3 ml	heated reagent position
SUB Substrate		2 x 3 ml	heated reagent position
CAL Calibrator	35500	4 x 1 ml	-
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	-
Cuvette bag with separate mixer	15660/11	500 pcs	-
Cuvette bag with separate mixer	15660/12	5 x 500 pcs	-
Reducer Ring	15660/52	2pcs	(Standard accessory HumaClot Duo Plus / Quattro)

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]
Hemostat Antithrombin Liquid	
RG1 Antithrombin Reagent at 37°C	3
SUB Substrate at 37°C	6

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			
Triglycerides	mg/dl	3500	Spiked normal plasma
Hemoglobin	mg/dl	1000	Spiked normal plasma
Bilirubin	mg/dl	40	Spiked normal plasma

Measuring Range	
Output Range	11% to 130%

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.

Pipetting Scheme

Sample Pre-Dilution	
Sample	10 µl
0,9% NaCl (0,154mol/l)	100 µl
Pipetting	
HumaClot Duo Plus and HumaClot Quattro: pre-warm RGT, SUB and cuvettes at 37°C. HumaClot Junior: pre-warm RGT 2 cuvettes at 37°C.	
pre-diluted sample	33 µl
RGT1 (FXa)	105 µl
<i>Transfer cuvette with sample and RGT1 into the measuring channel</i>	
Inkubation time	180 s
Start Reagent RGT2 (SUB)	30 µl
Autostart	yes

Reagent Settings

Test Hemostat AT	
(Full Setup, User) <AT>+Enter-Key=CuvIN or Pat-ID+0-key	
Method Store	6
'AT'	
Date	Will be displayed
Measuring Time	65 s
Gain_idx	0
Cuv in	ON
Reg_sens	ON
Start Reagent	
LOT	Please insert LOT
Volume	30 µl
incu	180 s

Clotting	OFF
Kin/ Dif	ON
3 rd convers	INTERPOLAT.
88 %	286.0 mE/min
44 %	459.0 mE/min
22 %	541.0 mE/min
11 %	583.0 mE/min

Standard Curve Calibration

A new standard curve must be established when changing a reagent LOT, after major maintenance or service, if indicated by quality control results and when required by laboratory control procedures and/or government regulations.

Preparation of Dilutions				
	% AT	Hemostat Calibrator	0.9 % NaCl	Dilution
Cal 1*	2	5.14	0	200 µl [CAL] + 200 µl NaCl
Cal 1	1.33	3.42	100 µl	
Cal 2	1	2.57	100 µl	
Cal 3	0.67	1.72	100 µl	

*The LOT-specific calibrator value can be found on the table of analytical values of the calibration kit.

Performance Characteristics

Method Comparison			
Test device	Predicate device	Regression equation	r
Hemostat AT / Junior	Hemostat AT /HC Pro	$y=0.9305x+1.9274$	0.9942
Hemostat AT / Duo Plus		$y=0.9544x+0.5892$	0.9927
Hemostat AT / Quattro		$y=0.9434x+0.0931$	0.9941

Precision				
		Within Run CV (%)	Run to Run CV (%)	Total CV (%)
HumaClot Junior				
BioRad Lyphocheck Coagulation Control	Level 1	Max: 2.37	0.46	5.11
	Level 2	Max: 2.26	0.42	5.70
	Level 3	Max: 3.89	0.79	3.95
HumaClot Duo Plus				
BioRad Lyphocheck Coagulation Control	Level 1	Max: 1.87	0.39	2.05
	Level 2	Max: 1.79	0.25	2.45
	Level 3	Max: 3.56	0.42	6.44
HumaClot Quattro				
BioRad Lyphocheck Coagulation Control	Level 1	Max: 2.05	0.51	5.05
	Level 2	Max: 4.59	0.77	6.83
	Level 3	Max : 6.32	0.87	10.26

