

Application Sheet for Antithrombin with HEMOSTAT Antithrombin^{liquid}

HumaCLOT Pro **REF** 15800

For additional information, please refer to the Operators Manual of the analyzer 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 HumaClot Pro, 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 Antithrombin ^{liquid}	36102		
RGT Antithrombin Reagent		4 x 3 ml	R4-R15
SUB Substrate		2 x 3 ml	R4-R15
CAL HEMOSTAT Calibrator	35500	4 x 1 ml	C1 in Sample Cup
CPN HEMOSTAT Control Plasma Normal	35001	6 x 1 ml	Sample rack position 01-22 or
CPA HEMOSTAT Control Plasma Abnormal	35002	6 x 1 ml	Position C3-C8 (when using QC-program)
NaCl 0.9% Sodium Chloride	-	4 ml	R4-R15
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" or	15800/25	4 ml	C2 empty Sample Cup for
Sample Cups (500 pcs) "Hitachi"	17470/59	2 ml	Calibration-
Empty vials (50 x 5ml)	15800/40		For NaCl R4-R15

Transfer at least 4 ml **NaCl** in an empty vial (REF 15800/40) before placing the vial on the instrument. Discard the remaining **NaCl** of the vial after use.

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.

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.

On-Board Stability

Material	Name in Test Protocol	Listed in the Test Setting as	Time [h]
Hemostat Antithrombin ^{liquid}			
[RGT] Antithrombin Reagent	AT liquid RGT	Reagent 2	12
[SUB] Substrate	AT liquid SUB	Start-Reagent	24
[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.

To optimize the use of [RGT] and [SUB] the following usage is recommended:

1. Possibility: In the original vial [RGT] can be stored on and off the instrument for intervals of 4x3 hours over a maximum period of 6 days. [SUB] can be stored on and off the instrument for intervals of 8x3 hours over a maximum period of 10 days.
2. Possibility: In the original vial [RGT] can be stored on and off the instrument for intervals of 8 x 1.5 hours over a maximum period of 10 days. [SUB] can be stored on and off the instrument for intervals of 15x 1.5 hours over a maximum period of 20 days.

Enter the LOT numbers into the reagent settings.

Reagent Settings

Reagent Setup			
[REF]	36102		
Test	HEMOSTAT Antithrombin		
Test Setup	Hemostat AT liq		
Reagent Name	AT liquid RGT	AT liquid SUB	NaCl DIL
Position in List	12	13	10
Abbreviation	ATrgt	ATsub	NaCl
LOT	<u>Please insert Lot number</u>	<u>Please insert Lot number</u>	<u>Please insert Lot number</u>
Vial	5ml-HumGL*	5ml-HumGL*	5ml-HumPL*

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

Interference Studies

No Interference up to			
Lipids	mg/dl	600	spiked normal plasma
Hemoglobin	mg/dl	600	spiked normal plasma
Bilirubin	mg/dl	50	spiked normal plasma

Measurement

Measuring Range			
Valid Clotting		Output Range	5.4% to 120%

Calibration Setting

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

Calibration Settings

Test Hemostat AT liq	
Field Name	Settings
1 st conversion	Interpolation
Unit conversion	mE / min -> %
Mode: in/out	lin -> lin
Output Format	xxxx.x
2 nd conversion	none
Auto-Calibration	
Diluent	NaCl
Determination	1
Cup	Human
Calibration Values	
0	100.0 %
1	50.0 %
2	25.0 %
3	12.5 %
4	6.25 %
Standard	
Concentration	<u>Please insert concentration (%)*</u>
Name	Hemostat CAL
LOT	<u>Please insert LOT Number</u>
Convers. range	5.4 % - 120 %

*refer to the Table of Analytical Values for the LOT-specific calibrator value