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 position C3-C8 (when using QC-program)
CPA **HEMOSTAT Control Plasma Abnormal**	35002	6 x 1 ml	
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 Sample Cups (500 pcs) "Hitachi"	15800/25 17470/59	4 ml 2 ml	C2 empty Sample Cup for Calibration-
Empty vials (50 x 5ml)	15800/40		For NaCl R4-R15

Additional Notes

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.
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]
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.

Reagent Settings

Enter the LOT numbers into the 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	*Please insert LOT number*	*Please insert LOT number*	*Please insert LOT number*
Vial	5ml-HumGL*	5ml-HumGL*	5ml-HumPL**

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

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

Interference Studies

No interference up to …					
Bilirubin	mg/dl	50	spiked normal plasma	50	spiked pathological plasma
Hemoglobin	mg/dl	1000	spiked normal plasma	1000	spiked pathological plasma
Lipids	mg/dl	1000	spiked normal plasma	1000	spiked pathological plasma

Performance Characteristics

Measuring Range			
Valid Clotting		**Output Range**	5.4% to 120%

Reference Interval

The following data was obtained with a specific HEMOSTAT Antithrombin liquid LOT using normal plasma according to EP28-A3.

HumaClot Pro	Median	95% Reference interval	
		2.5th Percentile	97.5th Percentile
164 samples	101 %	79.4 %	127 %

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.

Standard Curve Calibration

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

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

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