Application Sheet for Thrombin Time with HEMOSTAT Thrombin Time

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 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 for use with the reagent and instrument system; other combinations are not validated or supported.

Material Required

Material	REF	Size	On-Board Position
HEMOSTAT Thrombin Time	34002		
RGT **Thrombin reagent**		3 x 3 ml	R4-R15
CPN **HEMOSTAT Control Plasma Normal**	35001	6 x 1 ml	Sample rack position 01-22 or position C5 (when using QC-program)
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	- -

Additional Notes

The required control has to be transferred into appropriate sample cups.

On-Board Stability

Material	Name in the Test Protocol	Listed in the Test Setting as	Time [h]
HEMOSTAT Thrombin Time			
RGT **Thrombin reagent**	Thrombin T RGT	Start-Reagent	24
CPN **HEMOSTAT Control Plasma Normal**	-	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.

Reagent Setup	
REF	**34002**
Test	HEMOSTAT Thrombin Time
Test Setup	Hemostat TT Scr or Hemostat TT ext
Reagent Name	Thrombin T RGT
Position in List	6
Abbreviation	TT-SC or TT-EX
LOT	*Please insert LOT-number*
Vial	5ml-HumGL*

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

Interference Studies

No interference up to ...					
Bilirubin	mg/dl	23.8	spiked normal plasma	14.8	spiked pathological plasma
Hemoglobin	mg/dl	197	spiked normal plasma	174	spiked pathological plasma
Lipids	mg/dl	125	spiked normal plasma	125	spiked pathological plasma

Performance Characteristics

Measuring Range	
Valid Clotting for screening Test TT scr	6 - 45 s
Valid Clotting for extended Test TT ext	6 - 300 s

Reference Interval

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

HumaClot Pro	Median	95 % Reference interval	
		2.5th Percentile	97.5th Percentile
167 samples	15.6 s	13.3 s	18.7 s

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.

Calibration Settings

HEMOSTAT Thrombin Time is a non-calibrated test.

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