

## Application Sheet for Thrombin Time (TT) with HEMOSTAT Thrombin Time

<b>HumaClot Junior</b> (model HC1)	<b>REF 18680</b>
<b>HumaClot Duo Plus</b> (model HC2)	<b>REF 15650</b>
<b>HumaClot Quattro</b>	<b>REF 15660</b>

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 the 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.

For additional information, please refer to the respective User Manual of the instrument and check current instructions for use (IFU) for reagents, controls and tables of assigned values.

Typical performance data can be found in the Verification Report of the respective instrument, accessible via

[www.human.de/data/gb/vr/18680.pdf](http://www.human.de/data/gb/vr/18680.pdf)

[www.human.de/data/gb/vr/15650.pdf](http://www.human.de/data/gb/vr/15650.pdf)

[www.human.de/data/gb/vr/15660.pdf](http://www.human.de/data/gb/vr/15660.pdf)

If the performance data are not accessible via internet, they can be obtained free of charge from your local distributor.

### Material Required

Material	REF	Size	On-Board Position
HEMOSTAT Thrombin Time	34002		
<b>RGT</b> Thrombin reagent		3 x 3 ml	Beside the analyzer
<b>CPN</b> HEMOSTAT Control Plasma Normal	35001	6 x 1 ml	-
Cuvettes with pre-filled mixers	15660/10	5 x 100 pcs	Pre-heated cuvette positions
Cuvette bag with separate mixer	15660/11	500 pcs	
Cuvette bag with separate mixer	15660/12	5 x 500 pcs	

### Pipetting Scheme

Pipetting	
<i>Pre-warm <b>RGT</b> Thrombin reagent (reconstituted) at room temperature and cuvettes at 37°C</i>	
1. Sample	75 µl
<i>Transfer cuvette with sample into a measuring channel</i>	
Incubation time	60 s
<b>2. Start reagent <b>RGT</b> Thrombin reagent</b>	<b>75 µl</b>
Auto start	yes

### Calibration Settings

HEMOSTAT Thrombin Time is a non-calibrated test.

### On-Board Stability

Material	Time [h]
<b>RGT</b> Thrombin reagent at room temperature	24

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.

### Test Settings

Test Protocol_ Printed automatically with every change / new start	
<i>(Reduced Setup, User) &lt;TT&gt; + Enter-Key = CuvIN or Pat-ID + 0-key</i>	
Method Store	4
Thrombin T.	
Date	Will be displayed
Measuring Time	301 s
Gain_idx	0
Cuv in	ON
Reag_sens	ON
Start Reagent	
LOT	Please insert LOT number
Volume	75 µl
Incubation	60 s
Clotting	ON
1 <sup>st</sup> conversion	NONE
2 <sup>nd</sup> conversion	NONE

### Interference Studies

No interference up to ...					
<b>Bilirubin</b>	mg/dl	37.5	spiked normal plasma	20	spiked pathological plasma
<b>Hemoglobin</b>	mg/dl	300	spiked normal plasma	400	spiked pathological plasma
<b>Lipids</b>	mg/dl	451	spiked normal plasma	172	spiked pathological plasma

### Performance Characteristics

Measuring interval	
Valid Clotting for Test Thrombin Time	10.1 - 300 s

Reference Interval			
The following data was obtained with a specific HEMOSTAT Thrombin Time LOT using normal plasma according to EP28-A3.			
HumaClot Quattro	Median	95% Reference interval	
		2.5th Percentile	97.5th Percentile
168 samples	13.3 s	11.5 s	15.9 s
<p><i>Please note: The 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.</i></p> <p>For more information how to establish reference intervals see CLSI document C28-A3.</p>			



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