

Application Sheet for Prothrombin Time (PT) with Hemostat Thromboplastin-SI

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 Thromboplastin-SI	31002		
[RGT] Thromboplastin reagent		6 x 2 ml	Reagent position left with magnetic stirrer and reducer ring (HC Duo Plus / Quattro)
[BUF] Reconstitution medium		6 x 2 ml	for reconstitution of [RGT]
HEMOSTAT Thromboplastin-SI	31003		
[RGT] Thromboplastin reagent		6 x 10 ml	Reagent position left with magnetic stirrer (HC Duo Plus / Quattro)
[BUF] Reconstitution medium		6 x 10 ml	for reconstitution of [RGT] only
[CAL] HEMOSTAT Calibrator	35500	4 x 1 ml	-
[NaCl] 0.9% Sodium Chloride	-		for dilution of calibrator
[CPN] HEMOSTAT Control Plasma Normal	35001	6 x 1 ml	-
[CPA] HEMOSTAT Control Plasma Abnormal	35002	6 x 1 ml	-
Cuvettes dispo incl. mixer	15660/10	5 x 100 pcs	Incubation block
Cuvettes bag incl. mixer	15660/11	500 pcs	
Cuvettes bag incl. mixer	15660/12	5 x 500 pcs	
Reducer Ring	15660/52	2pcs	Standard accessory HumaCLOT Duo Plus/ Quattro
Magnetic stirrer	15660/50	10pcs	(to be cleaned with HumaClot Pro Wash Solution; REF 15800/20)

Interference Studies

No interference up to ...			
Lipids	mg/dl	600	spiked normal and pathological plasma
Hemoglobin	mg/dl	500	spiked normal and pathological plasma
Bilirubin	mg/dl	50	spiked normal and pathological plasma

On-Board Stability

Material	Time [h]
Thromboplastin reagent (reconstituted)	16 (10 ml) 8 (2 ml)
HEMOSTAT Control Plasma Normal	4
HEMOSTAT Control Plasma Abnormal	4
HEMOSTAT Calibrator	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.

Pipetting Scheme

Pipetting Scheme	
<i>Pre-warm RGT and cuvettes at 37°C</i>	
1. Sample	50 µl
<i>Transfer cuvette with sample to a measuring position</i>	
Incubation time	60 s
2. Start reagent RGT	100 µl
Auto start	yes

Test Settings

Test Protocol	
<i>(Full Setup, User) <1>+Enter-Key=CuvIN or Pat-ID + 0-Key</i>	
Method store	1
PT	
Date	Will be displayed
Meas.time	81 s
Gain_idx	0
Cuv in	ON
Reag_sens	OFF
Start Reagent	
LOT	Please insert LOT
Volume	100 µl
incubation	60 s
clotting	ON
Kin/Dif	OFF
1st conversion	INTERPOLAT.
92 %	Insert LOT-specific calibration value Cal 1* and s
46.0 %	Insert LOT-specific calibration value Cal 2* and s
23.0 %	Insert LOT-specific calibration value Cal 3* and s
11.5 %	Insert LOT-specific calibration value Cal 4* and s
0 %	n.a.
2nd conversion	INR
ISI	Insert LOT-specific ISI for models HC 1, HC 2 or HC 4

*LOT-specific analytical value of the calibrator. It can be found on the table of analytical values in the calibrator kit (REF 35500).

Needs to be calculated with every new calibrator LOT and inserted to the instrument.

Standard Curve Calibration

A new standard curve must be established when

- changing to a new PT reagent lot
- after major maintenance or service
- if indicated by quality control results
- when required by laboratory control procedures and/or governmental regulations.

The following steps have to be followed:

- a) Reconstitution of the calibrator (REF 35500) with 1 ml of distilled or deionized water without preservatives, as mentioned in the instruction for use (IFU) of the calibrator kit (REF 35500).
- b) Insertion of the analytical value into the instrument (see *). The LOT-specific %-value can be found with the analytical value sheet in the Hemostat Calibrator kit (REF 35500).
- c) Calculation of the respective % Quick-value for Cal 2, Cal 3 and Cal 4 (always 50% of the previous value). Subsequent introduction of the calculated values into the instrument (see #).
- d) For preparation of the dilution levels of the calibrator please see an example in the table below.
- e) Run the prepared calibrator levels including Cal 1. Insert the results into the instrument. To do so, chose the test *PT* by pressing  (the prompt "cuv(ette) in" appears). Press the -key, enter the first data point and press . Repeat this process until all calibration points are inserted. Please note, the 5th calibration point must be 0.
- f) Add ISI and LOT number of start reagent from LOT-specific analytical value sheet and press  to save new parameters

Alternative: Enter calibration data as described in the User Manual pp 40-41.

Please note: the determination of an MNPT value is not needed when calibrating with the HEMOSTAT Calibrator.

Example with a calibrator showing an analytical value of 92%:

Preparation of Calibrator Dilutions				
	Cal 1	Cal 2	Cal 3	Cal 4
% PT* (% Quick)	92*	46 [#]	23 [#]	11.5 [#]
HEMOSTAT Calibrator	400µl	400µl of Cal 1	400µl of Cal 2	400µl of Cal 3
0.9 % NaCl	0µl	400 µl	400 µl	400 µl

*LOT-specific analytical value of the calibrator. It can be found on the table of analytical values in the calibrator kit (REF 35500).

Needs to be calculated with every new calibrator LOT and inserted to the instrument.

Performance Characteristics

Measuring Range	
Valid Clotting	9 - 80 sec

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.