Application Sheet for Fibrinogen with Hemostat Fibrinogen (REF 32002)

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 Fibrinogen	32002		
RGT **Fibrinogen Reagent**		2 ml	beside the analyzer
BUF **Imidazole Buffered Saline**		4 ml	beside the analyzer
CAL **Fibrinogen Reference Plasma**		1 ml	-
CPN **Hemostat Control Plasma Normal**	35001	6 x 1 ml	-
CPA **Hemostat Control Plasma Abnormal**	35002	6 x 1 ml	
Cuvettes with prefilled mixers	15660/10	5*100 pcs	- -
Cuvette bag with separate mixer	15660/11	500 pcs	-
Cuvette bag with separate mixer	15660/12	5*500 pcs	-

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.

On-Board Stability

Material	Time [h]
Hemostat Fibrinogen	
RGT **Fibrinogen reagent at RT**	72
BUF **Imidazole Buffered Saline at RT**	48
Hemostat Control Plasma Normal	4
Hemostat Control Plasma Abnormal	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.

Interference Studies

No interference up to			
Triglycerides	mg/dl	1000	Spiked normal plasma
Hemoglobin	mg/dl	1000	Spiked normal plasma
Bilirubin	mg/dl	50	Spiked normal plasma

Measuring Range			
Valid Clotting	5-100 sec	**Output Range**	0.7 g/l to 6.0 g/l

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.

Pipetting Scheme

Sample Pre-dilution (1:20)	
Sample, control	10 µl
BUF (Imidazole Buffer)	190 µl
Pipetting Scheme	
Pre-warm RGT at RT and sample test cups at 37°C	
1.Pre-dilute sample	100 µl
Transfer measuring cup with sample to a measuring position	
Incubation time	180 sec
2.Start reagent RGT (Hemostat Fibrinogen)	50 µl
Autostart	yes

Reagent Settings

Test Hemostat FIB	
(Full Setup, User) <FIB>+Enter-Key=CuvIN or Pat-ID+0-key	
Method Store	2
'Fib. g/l'	
Date	Will be displayed
Measuring Time	101 s
Gain_idx	0
Cuv in	On
Reg_sens	Off
Start Reagent	
LOT	Please insert LOT
Volume	50 µl
incu	120 s

Clotting	ON
Kin/ Dif	OFF
3nd convers	INTERPOLAT.
5.14 g/l	Insert s
3.42 g/l	Insert s
2.57 g/l	Insert s
1.72 g/l	Insert s
1.29 g/l	Insert s

Standard Curve Calibration

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

Preparation of Dilutions					
			Fib g/l	**Calibrator***	**Imidazole**
Cal 1	1:10	2	5.14	540	60
Cal 2	1:15	1.33	3.42	560	40
Cal 3	1:20	1	2.57	570	30
Cal 4	1:30	0.67	1.72	580	20
Cal 5	1:40	0.5	1.29	585	15

* The LOT-specific calibration value can be found on the table of analytical values of the calibration kit.

Performance Characteristics

Method Comparison			
Test Device	**Predicate Device**	**Regression Equation**	**r**
Hemostat Fib / Junior	Hemostat Fib /HC Pro	y=1.0433x-0.1983	0.9859
Hemostat Fib / Duo Plus		y=0.9617x-0.0479	0.9914
Hemostat Fib / Quattro		y=0.9244x+0.1408	0.9916

Precision				
		Within Run CV (%)	**Run to Run CV (%)**	**Total CV (%)**
HumaClot Junior				
BioRad Lyphocheck Coagulation Control	Level 1	Max :3.8	0.52	3.3
	Level 2	Max : 7.2	1.46	5.9
	Level 3	Max : 12.4	2.35	10.3
HumaClot Duo Plus				
BioRad Lyphocheck Coagulation Control	Level 1	Max : 4.0	0.57	3.1
	Level 2	Max : 6.0	1.20	5.1
	Level 3	Max : 8.4	1.42	6.9
HumaClot Quattro				
BioRad Lyphocheck Coagulation Control	Level 1	Max : 3.7	0.68	2.8
	Level 2	Max : 5.7	0.88	4.7
	Level 3	Max : 10.0	1.42	9.0

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