Application Sheet for Fibrinogen with Hemostat Fibrinogen

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 Fibrinogen	32002		
RGT **Fibrinogen reagent**		2 ml	R4-R15
BUF **Imidazole buffered saline**		pour 4 ml into empty vials	R4-R15 and C2 in cup for calibration
CAL **Fibrinogen reference plasma**		1 ml	C1
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	
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	- -
Empty vials (50 x 5ml)	15800/40		For BUF R4-R15

Transfer at least 4 ml BUF in an empty vial (REF 15800/40) before placing the vial on the instrument. Discard the remaining BUF of the vial, after use.

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	Name in Test Protocol	Listed in the Test Setting as	Time [h]
Hemostat Fibrinogen			
RGT **Fibrinogen Reagent**	Fib RGT	Start-Reag	72
BUF **Imidazole Buffered Saline**	Fib BUF	Buffer / Diluent	48
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.

Interference Studies

No Interference up to			
Triglycerides	mg/dl	800	Spiked normal plasma
Hemoglobin	mg/dl	500	Hemolysed plasma
Bilirubin	mg/dl	12	Icteric plasma

Measuring Range			
Valid Clotting	3-120 s	Output Range	0.2 g/l to 6.0 6/l

Reference Interval			
n=49			
Mean	3.2 g/l	Median	3.06 g/l
-2SD	1.99 g/l	5^{th} Percentile	2.3 g/l
+2SD	4.3 g/l	95^{th} Percentile	4.0 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.

Reagent Settings

Screen Edit Reagent		
REF	**32002**	
Hemostat Test	Hemostat Fibrinogen	Hemostat Fibrinogen
Reagent Name	Fib RGT	Fib BUF
Position in List	4	5
Abbreviation	Fib	FiBUF
LOT	Please insert Lot number	Please insert Lot number
Vial	5ml-HumGL*	5ml-HumPL*

*5ml-HumGL (5ml HUMAN Glass Bottle), 5ml-HumPL (5ml HUMAN Plastic Bottle)

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 Fib	
Field Name	**Settings**
1st conversion	Interpolation
Unit conversion	sec -> %
Mode: in/out	log -> log
Output Format	xxx.xxx
2nd conversion	none
MNPT	-
Auto-Calibration	
Diluent	Fib BUF
Determination	1
Cup	Human
Calibration Values	
0	6.00 g/l
1	3.00 g/l
2	2.00 g/l
3	1.00 g/l
Standard	
Concentration	*Please insert concentration (%)**
Name	Fibrinogen Ref Plasma
LOT	*Please insert LOT Number*
Convers.range	0.200 g/l to 6.000 g/l

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

Performance Characteristics

Method Comparison		
Predicate Device	**Regression Equation**	**r**
Technoclone Fibrinogen on STA-R Evolution	0.8408x-0.0726	0.803

Precision				
		within run CV (%)	**run to run CV (%)**	**total CV (%)**
BioRad Lyphocheck Coagulation Control	Level 1 [g/l]	3.40	3.28	3.69
	Level 2 [g/l]	3.35	1.81	1.84
	Level 3 [g/l]	4.20	3.08	5.21

CE