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**		5 x 2 ml	R4-R15
BUF **Imidazole buffered saline**		1 x 100 ml	R4-R15 pour 4 ml into empty vial
CAL **Fibrinogen reference plasma**		2 x 1 ml	C1 in sample cup for calibration
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	
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	- -
Empty vials (50 x 5ml)	15800/40		For BUF R4-R15

Additional Notes

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

Reagent Settings

Enter the LOT numbers into the reagent settings.

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

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

**5 ml-HumPL (5ml HUMAN Plastic Bottle)

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 ...					
Bilirubin	mg/dl	50	spiked normal plasma	50	spiked pathological plasma
Hemoglobin	mg/dl	1000	spiked normal plasma	1000	spiked pathological plasma
Lipids	mg/dl	1000	spiked normal plasma	890	spiked pathological plasma

Performance Characteristics

Measuring Range			
Valid Clotting	5 - 120 s	Analytical measuring interval	0.7 g/l to 6.0 g/l
		Reportable interval	0.7 g/l to 12.0 g/l

The default measurements are within an analytical measuring interval of 0.7 to 6.0 g/l. The reportable interval can be extended by diluting a sample reported as > 6.00 g/l (> 600 mg/ dl) which is outside of the analytical measuring interval.
Re-Run the sample with manual 1:2 dilution with Fib BUF and measure immediately. The resulting value needs to be multiplied by 2 to obtain the correct value.
Samples below the measuring interval will be reported as < 0.7 g/l.

Reference Interval

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

HumaClot Pro	Median	95 % Reference interval	
		2.5th Percentile	97.5th Percentile
166 samples	3.04 g/l	2.02 g/l	4.21 g/l

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.

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	s -> g/l
Mode: in/out	log -> log
Output Format	xxx.xx
2nd conversion	none
Auto-Calibration	
Diluent	Fib BUF
Determination	1
Cup	Human/ Hitachi
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 (g/l)**
Name	Fibrinogen Ref Plasma
LOT	*Please insert LOT number*
Conversion range	0.70 g/l to 6.00 g/l

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

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