

Application Sheet for free Protein S with HEMOSTAT free Protein S

HumaClot Pro **REF** 15800

For additional information, please refer to the user 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 analyzer at

www.human.de/data/gb/vr/36201.pdf
www.human-de.com/data/gb/vr/36201.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 analyzer 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 analyser. Other combinations are not validated or supported.

Material Required

Material	REF	Size	On-Board Position
HEMOSTAT free Protein S	36201		
RG T free PS Latex Reagent		2 x 2.5 ml	R4-R15
BU F Reaction Buffer		2 x 4 ml	R4-R15
DIL Dilution Buffer		2 x 6.5 ml	R4-R15
CAL HEMOSTAT Calibrator	35500	4 x 1 ml	C1
CPN HEMOSTAT Control Plasma Normal	35001	6 x 1 ml	Sample rack position 01-22 or position C5-C6 (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	- -

Additional Notes

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]
[DIL] Diluent	fPS Diluent	Diluent	68
[BUF] Buffer	fPS Buffer	Reagent 1	68
[RGT] Latex Reagent	fPS Reagent	Start-Reagent	68
[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 (18 – 25°C). The above mentioned on-board stability values may deviate due to differences in laboratory environmental conditions.

To optimize the stability in applying HEMOSTAT free Protein S the following handling is recommended: Reagents in original vials may be continually used on-board (18 – 25°C) for 68 hours.

When used temporarily on-board (18 – 25°C), the stability can be extended for max. 3 weeks:

tests could be performed 2 days per week for max. 2 hours on-board, with an in-between storage at 2 – 8°C.

Reagent Settings

Enter the LOT numbers into the reagent settings.

Reagent Setup			
[REF]	36201		
Test	HEMOSTAT free Protein S		
Test Setup	Hemostat fPS		
Reagent Name	fPS Reagent [RGT]	fPS Buffer [BUF]	fPS Diluent [DIL]
Position in List	14	15	16
Abbreviation	PSrgt	PSbuf	PSdil
LOT	<i>Please insert LOT number</i>	<i>Please insert LOT number</i>	<i>Please insert LOT number</i>
Vial	5ml-HumGL*	5ml-HumGL*	5ml-HumPL**

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

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

Interference Studies

No Interference up to					
Bilirubin	mg/dl	50	spiked normal plasma	50	Spiked plasma with low protein S level
Hemoglobin	mg/dl	1000	spiked normal plasma	1000	Spiked plasma with low protein S level
Lipemia	mg/dl	400	spiked normal plasma	600	Spiked plasma with low protein S level
Rheumatoid Factors	mg/dl	450	spiked normal plasma	300	Spiked plasma with low protein S level

Performance Characteristics

Measuring Range

Valid Measurement		Output Range	10 % to 150%
-------------------	--	--------------	--------------

Reference Interval

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

HumaClot Pro	Median	95 % Reference interval	
		2.5th Percentile	97.5th Percentile
87 females	99.4 %	63.3 %	166 %
105 males	124 %	87.5 %	182 %

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 calibration curve should be established after 49 days when using the same reagent LOT. Additionally, a new calibration 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.

Calibration Settings

Test: HEMOSTAT free Protein S	
Field Name	Settings
1 st conversion	Interpolation
Unit conversion	mE / min -> %
Mode: in/out	lin -> lin
Output Format	xxxx.x
2 nd conversion	none
Auto-Calibration	
Diluent	Dilution Buffer [DIL]
Determination	1
Cup	Human/ Hitachi
Calibration Values	
0	10 %
1	30 %
2	60%
3	90 %
4	120 %
5	150 %
Standard	
Concentration	<u>Please insert concentration (%)</u> *
Name	HEMOSTAT Calibrator
LOT	<u>Please insert LOT number</u>
Conversion range	10 % - 150 %

* for the LOT-specific calibrator value refer to the table of analytical values in the HEMOSTAT Calibrator kit

