

Application Sheet for Protein S with HEMOSTAT free Protein S (REF 36201)

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/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 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 free Protein S	36201		
[RGT] free PS Latex Reagent		2 x 2.5 ml	-beside the analyzer
[BUF] Reaction Buffer		2 x 4 ml	-beside the analyzer
[DIL] Diluent		2 x 6,5 ml	-for mandatory sample dilution
[CAL] Calibrator	35500	4 x 1 ml	-
[CPN] HEMOSTAT Control Plasma Normal	35001	6 x 1 ml	
[CPA] HEMOSTAT Control Plasma Abnormal	35002	6 x 1 ml	-
Cuvettes with pre-filled mixers	15660/10	5 x 100 pcs	-
Cuvette bag with separate mixer	15660/11	500 pcs	-
Cuvette bag with separate mixer	15660/12	5 x 500 pcs	-

On-Board Stability

Material	Time [h]
HEMOSTAT free Protein S	
[RGT] free PS Latex Reagent	68
[BUF] Reaction Buffer	68
[DIL] Diluent	68

The stated stability data were established under controlled laboratory conditions (18 – 25°C). The above mentioned 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 at 18 – 25°C for 68 hours.

When used temporarily at 18 – 25°C, the stability can be extended for max. 3 weeks:

tests have to be performed 2 days per week for max. 2 hours at 18 – 25°C with an in-between storage at 2 – 8°C.

Pipetting Scheme

Please measure pre-diluted sample within 15 min, to avoid sample degradation and false too high results.

Sample Pre-Dilution (1:6)	
Sample, Control	25 µl
[DIL] free Protein S Diluent	125 µl
Pipetting	
Prewarm cuvettes at 37°C.	
1. [BUF] Reaction buffer	55 µl
2. Pre-diluted sample	25 µl
<i>Transfer cuvette with pre-diluted sample and reaction buffer into the measuring channel</i>	
Incubation time	120 s
3. Start Reagent [RCT] free PS Latex Reagent	70 µl
Autostart	yes

Test Settings

Test Protocol		(0 = OFF)
(Full Setup, experienced User) =Utilities /printer/parameter protocol/ actual method		
Method store		8
'fPS'		
Meas. Time		111 s
Gain_idx		0
Cuv in		ON
reag_sens		OFF
reag_mode		0
clot_mode		0
Start Reagent		
Lot		Please insert LOT
Volume		70 µl
Inc1		0 s
Inc2		120 s
Clotting		OFF
Kin/Dif		ON
Parameter Protocol		
	1st conversion	NONE
	2nd conversion	NONE
	MNPT	1.0 s
	ISI	0.01
	(->100%	1.0 s
	3rd conversion	INTERPOL.

	Format	xxx.x
	Min val.	10.0 %
	Max val.	130 %
	Input	LINEAR
	Output	LINEAR
	Tendency	RISING
Calibration	10%	Insert mE/min
	30%	Insert mE/min
	60%	Insert mE/min
	90%	Insert mE/min
	120%	Insert mE/min
Mixer	rpm1	800
	rpm2	0
	rpm1→rpm2	7 s
LED	wavelength	405 nm
raw value	Extinction Filter	6
Clotting	learn	1 s
	lag	15 s
	Filter	1
	Min Time	9.0 s
	Max Time	160.0 s
	Mult	20.000
Kin./Diff.	t1	60 s
	t2	110 s
	raw values	RISING
	Correl.	0.900

Test Protocol Printed automatically with every change / new start		
<i>(Reduced Setup, User) <8>+Enter-Key=cuv in or Pat-ID + 0-Key</i>		
Method store		8
'fPS'		
Date:		Will be displayed
Meas. Time		111 s
Gain_idx		0
Cuv in		ON
reag_sens		OFF
reag_mode		0
clot_mode		0
Start Reagent:		
Lot		Please insert LOT
Volume		70 µl
Inc2		120 s
Clotting		OFF
Kinetic		ON
Parameter Protocol		
3rd conversion		INTERPOLAT.

Calibration Curve	10%	Insert mE/min
	30%	Insert mE/min
	60%	Insert mE/min
	90%	Insert mE/min
	120%	Insert mE/min

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			
	[%] free PS	Volume [DIL] Diluent [μl]	Volume [CAL] Calibrator [μl]
Cal 1	120	= AV*6 – 120μl	120
Cal 2	90	= AV*6 – 90μl	90
Cal 3	60	= AV*6 – 60μl	60
Cal 4	30	= AV*6 – 30μl	30
Cal 5	10	= AV*6 – 10μl	10

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

Performance Characteristics

Interference Studies

No Interference up to			
Lipids	mg/dl	400	Spiked normal plasma
Hemoglobin	mg/dl	1000	Spiked normal plasma
Bilirubin	mg/dl	50	Spiked normal plasma

Measuring Range			
Valid Measurement		Output Range	10 % to 130%

The measuring range with HEMOSTAT free Protein S covers 10 % to 200 %. This total measuring range is obtained through additional sample Dilution.

For Example, if results of 1:6 Pre-diluted sample is < 10% or ERR lin, measure undiluted patient sample and divide obtained value by 6 to calculate correct free Protein S value.

Or if result is >130%, the sample might be further diluted 1:2 (total Pre-Dilution 1:12) to obtain actual free Protein S value. Multiply result by 2

