

Application Sheet for D-Dimer with HEMOSTAT D-Dimer

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 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	Position On-Board
HEMOSTAT D-DIMER	36002		
RG T D-Dimer Latex reagent		1ml	R4-R15
BU F Reaction buffer		2,5 ml	R4-R15
CA L Calibrator		1 ml	C1 in sample - cup
DI L Diluent		6 ml	C2 in sample - cup
HEMOSTAT D-DIMER Control High	36012	2 x 1 ml	Sample rack position 01-22 or position C3-C8 (when using QC-program)
HEMOSTAT D-DIMER Control Low	36012	2 x 1 ml	
Cuvette Ring	15800/10	6 x 10 x 32 pcs	Cuvette Ring Rotor
WA SH HumaClot Pro Wash Solution	15800/20	15 ml	W1
CL EAN HumaClot Pro Cleaner	15800/30	15 ml	W2
Sample Cups (2 x 250 pieces) „Human“or	15800/25	4 ml	-
Sample Cups (500 pieces)„Hitachi“	17470/59	2 ml	-

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 the Test Protocol	Listed in the Test Setting as	Time [h]
[RGT] D-Dimer Latex reagent	D-Dimer RGT	Start-Reagent	72
[BUF] Reaction buffer	D-Dimer BUF	Reagent 1	72
[DIL] Diluent	D-Dimer DIL	only for calibration	8
[CAL] Calibrator	D-Dimer CAL	only for calibration	8
HEMOSTAT D-DIMER Control High	-	Load as sample or as QC (when using QC-program)	8
HEMOSTAT D-DIMER Control Low	-	Load as sample or as QC (when using QC-program)	8

The above stated stability data was established under controlled laboratory conditions. The above-mentioned on-board stability values may deviate due to differences in laboratory environmental conditions.

Interference Studies

Threshold Values			
Lipids	mg/dl	57	spiked plasma
Hemoglobin	mg/dl	200	
Bilirubin	mg/dl	40	

Higher lipid values or turbid samples can result in falsely elevated or false low values. As a result, it is recommended to centrifuge lipemic patient samples at 15 000 x g for 10 minutes, prior to analysis.

Measuring Range	
Valid Range	150 ng/ml to 75000 ng/ml DDU

The total measuring range with HEMOSTAT D-DIMER covers 150 ng/ml DDU to 75.000 ng/ml DDU. This total measuring range is obtained through manual sample dilution, when the range of the calibration curve (220 ng/ml -2600 ng/ml) is exceeded.

Example 1: If the correct sample result of an undiluted patient sample is at e.g. 3600 ng/mL, then the result is shown as >2600 ng/ml. The sample needs to be re-run after manual 1:6 dilution. The obtained value needs to be multiplied by 6 to obtain the correct value.

Example 2: If the correct sample result of an undiluted patient sample is at e.g. approx. 17000 ng/mL, then the result is shown as “not linear” or >2600 ng/ml. After 1:6 dilution of the sample, the result, again, will be displayed as “not linear” or >2600 ng/ml. The 1:6 diluted sample, subsequently, needs to be diluted 1:8 in order to obtain a value that is within the calibration curve. This value needs to be multiplied by 48.

Samples with values below 150 ng/ml will be reported as <150.

Please Note: HEMOSTAT D-DIMER Diluent (DIL) needs to be used for all manual sample dilutions.

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 on how to establish reference intervals see CLSI document C28-A3.

Enter the LOT numbers into the reagent settings.

Reagent Settings

Screen Edit Reagent			
REF	36002		
Hemostat D-Dimer	Hemostat DDi	Hemostat DDi	Hemostat DDi
Reagent Name	D-Dimer RGT	D-Dimer BUF	D-Dimer DIL
Position in List	7	8	9
Abbreviation	DDRGT	DDBUF	DDDIL
LOT	<u>Please insert Lot number</u>	<u>Please insert Lot number</u>	<u>Please insert Lot number</u>
Vial	5ml-HumGL*	5ml-HumGL*	Sample cup 1 ml

*5ml-HumGL (5ml HUMAN Glass 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 DDi	
Field Name	Settings
1 st conversion	Interpolation
Unit conversion	mE/min -> ng/ml
Mode: in/out	lin -> lin
Output Format	xxxx.x
Auto-Calibration	
Diluent	D-Dimer DIL
Determination	2
Deviation	20%
Cup	Human
Calibration Values	
0	220 ng/ml
1	400 ng/ml
2	800 ng/ml
3	1600 ng/ml
4	2600 ng/ml
Standard	
Concentration	<u>Please insert concentration (ng/ml)*</u>
Name	Hemostat DD CAL
LOT	<u>Please insert LOT Number</u>
Convers.range	150 – 2600 ng/ml

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

