

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 | | |
| RGT D-Dimer Latex reagent | | 2 x 1 ml | R4-R15 |
| BUF Reaction buffer | | 2 x 2.5 ml | R4-R15 |
| CAL Calibrator | | 1 x 1 ml | C1 in sample - cup |
| DIL Diluent | | 1 x 6 ml | C2 in sample - cup |
| HEMOSTAT D-Dimer Control High | 36012 | 2 x 1 ml | Sample rack position 01-22 or position C7-C8 (when using QC-program) |
| HEMOSTAT D-Dimer Control Low | | 2 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 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.

Reagent Settings

Enter the LOT numbers into the reagent settings.

| Reagent Setup | | | |
|-------------------------|---------------------------------|---------------------------------|---------------------------------|
| [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 1-2 ml |

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

Interference Studies

| No interference up to ... | | | | | |
|---------------------------|-------|-----|----------------------------|-----|-------------------------------|
| Bilirubin | mg/dl | 10 | spiked low positive plasma | 25 | spiked highly positive plasma |
| Hemoglobin | mg/dl | 200 | | 200 | |
| Lipids | mg/dl | 69 | | 57 | |

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.

Performance Characteristics

| Measuring Range | |
|-------------------------------|------------------------------|
| Analytical measuring interval | 150 ng/ml to 2600 ng/ml DDU |
| Reportable interval | 150 ng/ml to 75000 ng/ml DDU |

The Analytical measuring interval, which is displayed on the instrument, is 150 ng/ml to 2600 ng/ml DDU. For sample results displaying "> 2600 ng/ml" DDU a manual dilution of the sample with HEMOSTAT D-Dimer Diluent needs to be done and re-measured. To obtain the true result of the diluted sample, the displayed result needs to be multiplied by the dilution factor.

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

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

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

| Reference Interval | |
|-----------------------------|-----------------------------------------------|
| Normal D-dimer level | |
| Adults | < 200 ng/ml DDU (equivalent to 500 ng/ml FEU) |

Please note:
The 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 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 or Hitachi |
| Calibration Values | |
| 0 | 220 ng/ml |
| 1 | 400 ng/ml |
| 2 | 800 ng/ml |
| 3 | 1600 ng/ml |
| 4 | 2600 ng/ml |
| Standard | |
| Concentration | <i>Please insert concentration (ng/ml)*</i> |
| Name | Hemostat DD CAL |
| LOT | <i>Please insert LOT number</i> |
| Conversion range | 150 – 2600 ng/ml |

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

