Determination of Factor VIII activity, Factor VIII inhibitors in human plasma and therapy monitoring with Thrombin Generation

HAEMOPHILIA A TESTING

A clear view into the future!
Lyophilized FVIII deficient plasma
- Immunodepleted or native
- < 1 IU/dL FVIII activity
- Fibrinogen and other factors (incl. VWF) are in normal range

**FVIII INHIBITOR ASSAY KIT**

Reagent Kit for the determination of Factor VIII Inhibitor according to the modified Bethesda method.

- Improved specificity in the lower range of antibody detection due to dilution with buffered FVIII – normal plasma (1 IU/ml FVIII:C)
- Kit contains **FVIII INH plasma** as a positive control and **FVIII INH free plasma** as a negative control
- Batch stable calibration curves on coagulation analyzers
- Calibrated against WHO standard
- **Results can be calculated directly** with an excel based calculation tool available in the customer area under www.technoclone.com
**TECHNOCHROM FVIII:C**

Technochrom FVIII:C kit contains all reagents and calibrators for chromogenic determination of factor VIII activity

- Automated on haemostasis or ELISA analysers
- Testkit including calibrators
- One calibration per lot
- High reagent stability
- High linearity (0 - 144 % FVIII activity)
- LLoQ < 1.0IU/dl

**Automated on Ceveron t100 / Ceveron s100**

The Ceveron TGA RB Kit, for the measurement of bleeding tendencies, is optimized for the fully automated CE marked measurement of Thrombin Generation on Ceveron t100 and Ceveron s100:

- Easy as a routine assay
  - (Measurement from the same patient sample as a routine parameter)
- Parallel testing of routine & thrombin generation samples
- Precise (intra/inter-assay CV < 5%)
- Fast (short assay time of ~20 min for Peak Thrombin)
- Automated normalisation
- Up to 36 samples in a single run

**THROMBIN GENERATION**

CEVERON TGA RB Kit with Low concentration of phospholipid micelles and rhTF for monitoring the procoagulant response to replacement therapies and for therapy monitoring with:

- Factor concentrates; native and recombinant
- Modified coagulation factors
- Alternative approaches like Emicizumab

Due to the reagent composition the assay can be used for FVIII determination in FVIII INH assay for patients under Emicizumab treatment!
### FVIII DEFICIENT PLASMA

<table>
<thead>
<tr>
<th>Product</th>
<th>Contents</th>
<th>REF</th>
<th>Package</th>
</tr>
</thead>
<tbody>
<tr>
<td>Factor VIII deficient plasma</td>
<td>Lyophilized Factor VIII deficient plasma, immunodepleted</td>
<td>5154002</td>
<td>5 x 1 ml</td>
</tr>
<tr>
<td></td>
<td>Lyophilized Factor VIII deficient plasma, native</td>
<td>5154007</td>
<td>5 x 1 ml</td>
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<tr>
<td></td>
<td></td>
<td>5154016</td>
<td>50 x 1 ml</td>
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</tbody>
</table>

### FVIII INHIBITOR ASSAY KIT

| FVIII Inhibitor Kit                  | 2 x ~ 3 ml Factor VIII Normal Plasma                      | 5152005 | ~ 2-4 tests |
|                                      | 1 x 1 ml F VIII Inhibitor Plasma                          |       |            |
|                                      | 1 x 1 ml Inhibitor Free Plasma                            |       |            |
|                                      | 1 x 17 ml Imidazole Buffer                                |       |            |

| FVIII Inhibitor Kit HCV neg.         | 2 x ~ 3 ml Factor VIII Normal Plasma                      | 5152009 | ~ 2-4 tests |
|                                      | 1 x 1 ml F VIII Inhibitor Plasma HCV neg.                 |       |            |
|                                      | 1 x 1 ml Inhibitor Free Plasma                            |       |            |
|                                      | 1 x 17 ml Imidazole Buffer                                |       |            |

| Controls                             |                                                           |       |            |
| FVIII Inhibitor Plasma               | Native Factor VIII Inhibitor Plasma for control of FVIII Inhibitor determination | 5159008 | 5 x 1 ml  |
| FVIII Inhibitor Plasma HCV neg.      | Factor VIII Inhibitor plasma for control of FVIII Inhibitor determination | 5159010 | 5 x 1 ml  |

### THROMBIN GENERATION

**Ceveron TGA RB Kit**

- 2 x 1 ml Ceveron TGA Reagent RB
- 2 x 3 ml Ceveron TGA Substrate
- 2 x 1.5 ml Ceveron TGA Reaction Buffer
- 2 x 1 ml Ceveron TGA Control Low
- 2 x 1 ml Ceveron TGA Control High
- 1 x 25 ml CaCl\(_2\) 25 mM

5006011 120 tests

### TECHNOCHROM FVIII:C

**TECHNOCHROM FVIII:C**

- 2 x 2 ml Substrate
- 2 x 2 ml Reagent A
- 2 x 2 ml Reagent B
- 4 x 1 ml Reference Standards FVIII (1-4)
- 3 x 30 ml FVIII Dilution Buffer
- 2 x 8 ml FVIII Reaction Buffer

5344101 ~ 40 tests

**TECHNOCHROM FVIII:C**

- Ceveron alpha and 100 series

- 2 x 2 ml Substrate
- 2 x 2 ml Reagent A
- 2 x 2 ml Reagent B
- 4 x 1 ml Reference Standards FVIII (1-4)
- 2 x 20 ml FVIII Dilution Buffer
- 2 x 8 ml FVIII Reaction Buffer

5344103 ~ 80 tests