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# HAEMOPHILIA A TESTING

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

*A clear view into the future!*

# FVIII DEFICIENT PLASMA

## 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

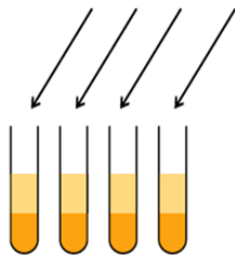
Reagent Kit for the determination of Factor VIII Inhibitor according to the modified Bethesda method.

- 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](http://www.technoclone.com)

## Plasma Sample

Predilute in Buffer with BSA as appropriate

	undil.	1:2	1:4	1:8	1:16	1:32	1:64	1:128	1:256	B.U./ml
without F VIII Inh.	+	+								≤ 1
weak F VIII Inh.	+	+	+	+	+					≤ 10
strong F VIII Inh.				+	+	+	+	+	+	> 10



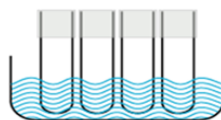
Mix each dilution 1 + 1 with buffered Normal Plasma (1IU FVIII/mL)

## Control Mixture

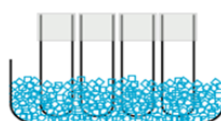


Mix buffered Normal Plasma (1IU FVIII/mL) 1 + 1 in Buffer with BSA

Cover tubes with parafilm



incubate in water bath for 2h at 37°



Stop incubation for at least 10 min in ice bath



Perform FVIII-activity assay and Calculate Bethesda units of sample

Demonstration video available on TECHNOZOOM Youtube Channel (QR-Code)



# 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

## 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

# 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

	Intra assay		Inter assay	
sample	sample 1	sample 2	sample 1	sample 2
n	12	12	6	6
Mean %	98,5	53,4	96,6	54,6
SD (%)	3,96	2,61	2,49	2,29
CV (%)	4,02	4,89	2,58	4,2

**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

Product	Contents	REF	Package
<b>Factor VIII deficient plasma</b>	Lyophilized Factor VIII deficient plasma, immunodepleted	5154002	5 x 1 ml
		5154004	50 x 1 ml
	Lyophilized Factor VIII deficient plasma, native	5154007	5 x 1 ml
		5154016	50 x 1 ml

## FVIII INHIBITOR ASSAY KIT

<b>FVIII Inhibitor Kit</b>	2 x ~ 3 ml Factor VIII Normal Plasma 1 x 1 ml F VIII Inhibitor Plasma 1 x 1 ml Inhibitor Free Plasma 1 x 17 ml Imidazole Buffer	5152005	~ 2-4 tests
<b>FVIII Inhibitor Kit HCV neg.</b>	2 x ~ 3 ml Factor VIII Normal Plasma 1 x 1 ml F VIII Inhibitor Plasma HCV neg. 1 x 1 ml Inhibitor Free Plasma 1 x 17 ml Imidazole Buffer	5152009	~ 2-4 tests
<b>Controls</b>			
<b>FVIII Inhibitor Plasma</b>	Native Factor VIII Inhibitor plasma for control of FVIII Inhibitor determination	5159008	5 x 1 ml
<b>FVIII Inhibitor Plasma HCV neg.</b>	Factor VIII Inhibitor plasma for control of FVIII Inhibitor determination	5159010	5 x 1 ml

## THROMBIN GENERATION

<b>Ceveron TGA RB Kit</b>	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 <sub>2</sub> 25 mM	5006011	120 tests
For measurement of <b>bleeding tendencies</b> . Low concentration of phospholipid micelles and low rhTF.			

## TECHNOCHROM FVIII:C

<b>TECHNOCHROM FVIII:C</b>	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
<b>TECHNOCHROM FVIII:C</b> 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

