

HAEMOPHILIA A RESEARCH

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

Research use only in the US and Canada.
Not for diagnostic procedures

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

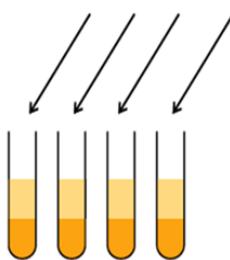
Reagent Kit for the determination of Factor VIII Inhibitor according to the modified Bethesda method.

- 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

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)

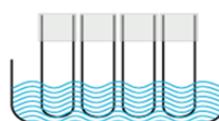
Control Mixture

Mix buffered Normal Plasma (1IU FVIII/mL)

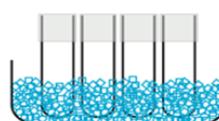
1 + 1 in Buffer with BSA



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

THROMBIN GENERATION

CEVERON® TGA RB Kit with Low concentration of phospholipid micelles and rhTF for researching the procoagulant response to potential replacement therapies 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 test 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, calibrator and controls for chromogenic determination of factor VIII activity

- automated on haemostasis or ELISA analysers
- test kit including calibrator and control material
- one calibration per lot
- high reagent stability
- High linearity (0 - 144 % FVIII activity)

sample	Intra assay		Inter assay	
	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 samples containing Emicizumab

THROMBIN GENERATION

Product	Contents	REF	Package
Ceveron® TGA RB Kit For measurement of bleeding tendencies . Low concentration of phospholipid micelles and low rhTF.	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

FVIII INHIBITOR ASSAY KIT

FVIII Inhibitor Kit	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
FVIII Inhibitor Kit HCV neg.	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

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

FVIII DEFICIENT PLASMA

Factor VIII deficient plasma	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

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	~ 160 tests
TECHNOCHROM® FVIII:C for Ceveron® alpha	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

All products are for research use only in the US and Canada

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