From the INNOVATION LEADER in Thrombosis & Hemostasis

More information on HYPHEN BioMed and product catalog is available at :
www.hyphen-biomed.com

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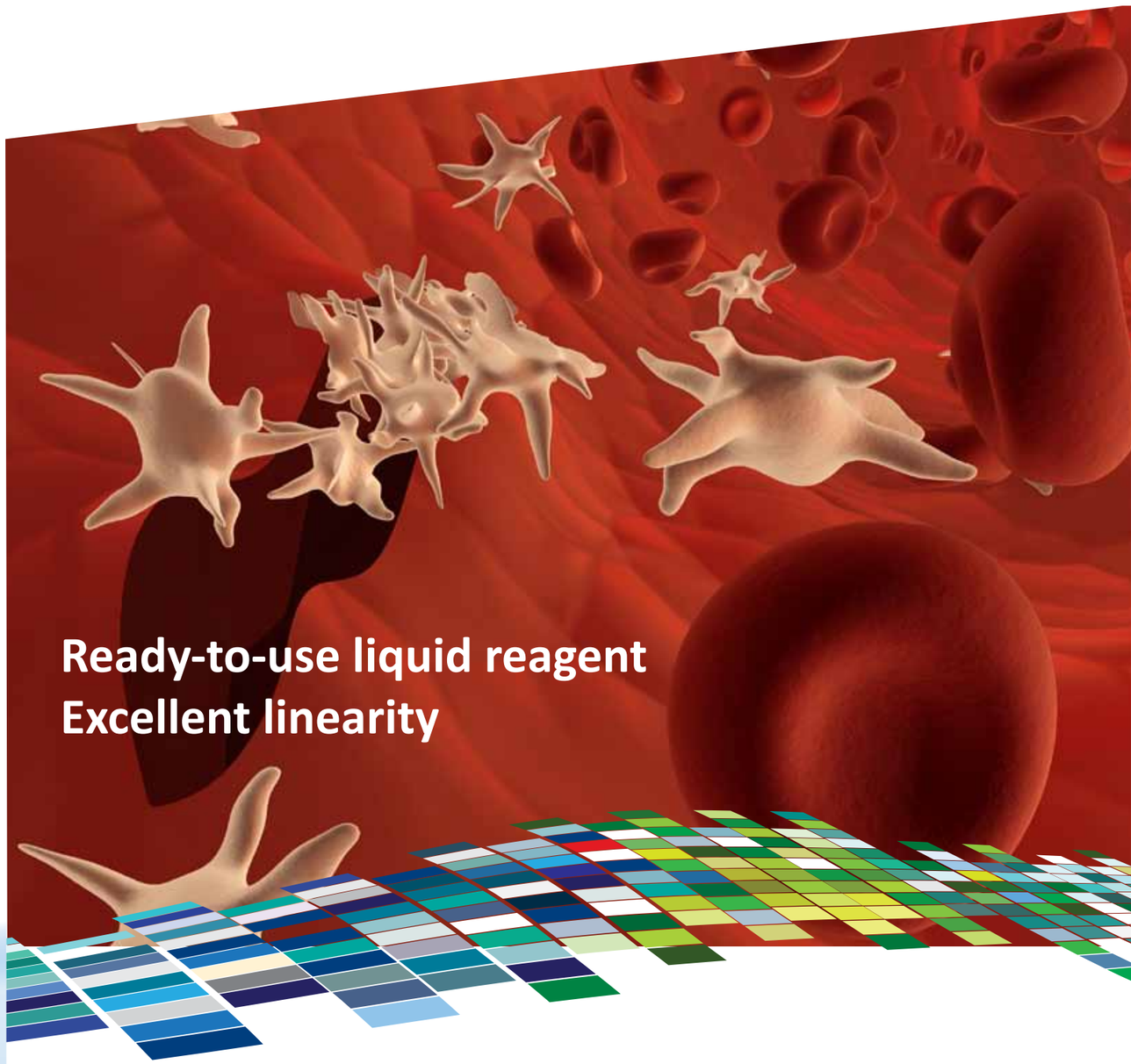
Lire attentivement les instructions figurant sur l'étiquetage et/ou la notice d'utilisation des réactifs.

HYPHEN BioMed
A Company of Sysmex Group

Immunoturbidimetric assay for quantification of vWF:Ag

LIAPHEN™ vWF:Ag



Ready-to-use liquid reagent
Excellent linearity

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vonWillebrand Disease (vWD) Assay Pannel

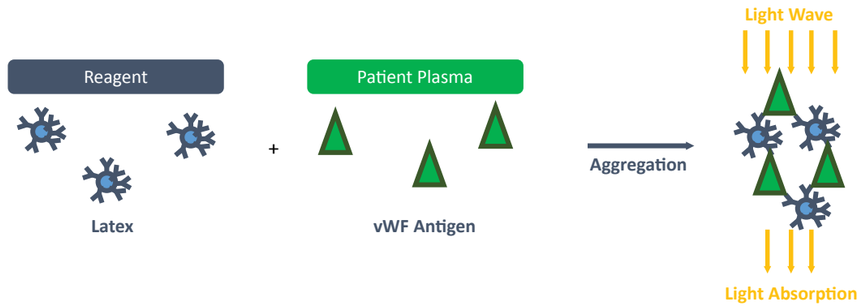
HYPHEN BioMed offers Laboratory assays for complete vWD profiling:

- Simple, easy, automatable assay
- High sensitivity for low vWF concentrations (vWD)
- Excellent linearity with extended dynamic range for high vWF concentrations (inflammation, liver diseases, prognosis)
- Automation protocols available for Sysmex CS series and STA-R

Reagent

Product name	Assay principle	Presentation	Ref. No.
LIAPHEN™ vWF:Ag *(CE-IVD)*	An immunoturbidimetric assay for in vitro quantitative determination of von Willebrand Factor Antigen (vWF:Ag) on human citrated plasma, using a manual or automated method. Reagents are in the liquid presentation, ready to use. R1: Reaction Buffer, liquid form. Contains BSA. R2: Latex, liquid form. Contains BSA.	R1: 4 x 5 mL R2: 4 x 6 mL	120206

Assay Principle



Classification of vWD subtypes

VWD is classified on the basis of criteria developed by the VWF Subcommittee of the ISTH, intending to be clinically relevant to the treatment of VWD. Diagnostic categories were defined that encompassed distinct pathophysiologic mechanisms and correlated with the response to treatment with DDAVP or blood products. [1,2]

	Type	Description
Quantitative	**Type 1**	Partial quantitative deficiency of vWF (most frequent).
	Type 3	Virtually complete deficiency of vWF
Qualitative	**Type 2**	Qualitative vWF defect (or abnormality)
	2A	Decreased vWF-dependent platelet adhesion with selective deficiency of high-molecular-weight multimers
	2B	Increased affinity for platelet GPIb
	2M	Decreased vWF-dependent platelet adhesion without selective deficiency of high-molecular-weight multimers
	2N	Markedly decreased binding affinity for FVIII

Performance Characteristics

** Example obtained with Sysmex CS-5100 (refer to the instrument specific method application)*

Precision

Control	Intra-assay				Inter-assay			
	N	Mean %	CV %	SD	N	Mean %	CV %	SD
Normal	40	102.8	2.2	2.3	30	103.4	2.2	2.3
Pathological	40	39.8	4.6	1.8	30	39.8	2.6	1.0

Limits

Analytical measurement zone	
Concentration vWF:Ag (%)	3 – 1600 *

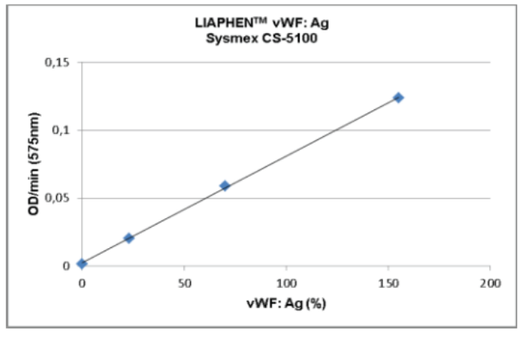
** with re-dilution*

Measurement range

Measurement Principle	Calibration Range	
Immunoturbidimetric method	Concentration of vWF:Ag (%)	0.0 – 154.7 *
	Raw values (OD/min)	0.0025 – 0.128 **

** Values are dependent of the calibrator*
*** values are given for information and may vary one batch to another and from one analyser to another*

Calibration curve



Calibrator and controls

Product name	Assay principle	Presentation	Ref. No.
BIOPHEN™ Plasma Calibrator *(CE-IVD)*	Normal human plasma for calibration of coagulation factors.	12 x 1 mL	222101
BIOPHEN™ Normal Control Plasma *(CE-IVD)*	Normal Control Plasma for coagulation assay quality control.	12 x 1 mL	223201
BIOPHEN™ Abnormal Control Plasma *(CE-IVD)*	Abnormal Control Plasma for coagulation assay quality control.	12 x 1 mL	223301

Other related products

Product name	Assay principle	Presentation	Ref. No.
ZYMUTEST™ vWF *(CE-IVD)*	An enzyme-immuno-assay for measuring human vWF in plasma, or in any fluid where vWF can be present.	96 tests	RK030A
ZYMUTEST™ vWF:CBA *(CE-IVD)*	A bio-immuno assay for measuring human vWF Collagen Binding Activity (CBA) in plasma, or in any fluid where vWF:CBA can be present.	96 tests	RK038A
BIOPHEN™ FVIII:C *(CE-IVD)*	A chromogenic assay for measuring the Factor VIII:C activity in human plasma or in Factor VIII:C concentrates, using a chromogenic method, manual or automated.	2 x 2.5 mL 2 x 6 mL	221402 221406
FVIII:C Deficient Plasma *(CE-IVD)*	A clotting assay for the measurement of Factor VIII:C activity in human citrated plasma, to be used in the presence of cephalin, activator and calcium (APTT reagent).	1 x 1 mL 6 x 1 mL	DP040A DP040K

Reference

1. Sadler JE, Budde U, Eikenboom JC, Favaloro EJ, Hill FG, Holmberg L, Ingerslev J, Lee CA, Lillicrap D, Mannucci PM, et al. Update on the pathophysiology and classification of von Willebrand disease: a report of the Subcommittee on von Willebrand Factor. J Thromb Haemost 2006 Oct;4(10):2103–2114
2. Favaloro EJ. New developments in the diagnosis and treatment of von Willebrand disease. Clin. Invest. 2012 2(8), 781–795