HEMOSIL® ACUSTAR
VON WILLEBRAND DISEASE ASSAY PANEL

A breakthrough in analytical sensitivity and simplicity.



FOR USE ON THE ACL AcuStar HEMOSTASIS TESTING SYSTEM

- **HemosIL AcuStar VWF:RCo**
  von Willebrand Factor Ristocetin Cofactor Activity
- **HemosIL AcuStar VWF:Ag**
  von Willebrand Factor Antigen

NEW

- **HemosIL AcuStar VWF:CB**
  von Willebrand Factor Collagen-Binding Activity

werfen

The first, and only, fully automated chemiluminescent von Willebrand Factor (VWF) assay panel for von Willebrand Disease (VWD) investigation

VWD testing demands accuracy, speed and efficiency. HemosIL AcuStar VWD assays offer the most innovative assay technology to achieve superior analytical sensitivity and unmatched simplicity—contributing to accurate, timely diagnosis.

HemosIL®



Unmatched analytical performance

- Chemiluminescent technology provides an expansive working range for high analytical sensitivity and precision
- Extended linearity range quantifies VWF levels < 1%
- VWF:RCo assay innovative recombinant technology* replaces platelets, enhancing accuracy
- Excellent agreement with immunoturbidimetric, ELISA and platelet-based methods

Simple and efficient

- Fully automated, pre-calibrated, ready-to-use reagent cartridges
- Up to eight-week onboard stability accommodates variable testing volume
- Results available on-demand 24 hours/day, 7 days/week
- Automated assays simplify results interpretation and reduce time- and labor-intensive manual methods

Complete solution for * VWD investigation

VWF testing on ACL AcuStar systems plus FVIII testing on ACL TOP® Family systems meet testing requirements approved by the British Committee for Standards in Haematology guidelines on VWD investigation for the diagnosis and management of VWD.1

*Patented and available only from IL.

VWD clinical overview

VWD is an inherited or acquired bleeding disorder

Causes

- Qualitative or quantitative defect of the VWF protein

Incidence/Prevalence

- Estimated 1% prevalence in worldwide population2
- The most common inherited bleeding disorder3
- Occurs in 1 out of every 100–1,000 people3
- Affects both genders

Clinical Events[2]

- Acquired VWD can be associated with serious autoimmune conditions (*e.g.*, systemic lupus erythematosus), heart disease or cancers
- Can develop with no underlying conditions3
- Mild-to-moderate Type 1 VWD is often undiagnosed until surgery or serious injury, due to mild symptoms

VWD patient profiles

Type	Phenotype	
1	Partial quantitative deficiency of VWF (~85% of confirmed cases)	Quantitative Deficiency of VWF
3	Virtually complete deficiency of VWF (< 1% of confirmed cases and is the most severe)	
2A	Decreased platelet-dependent function associated with the absence of high-molecular-weight (HMW) VWF multimers	Qualitative Deficiency of VWF (~15% of confirmed cases)
2B	Increased affinity for platelet GPIbα	
2M	Decreased platelet-dependent function not associated with absence of HMW VWF multimers	
2N	Markedly decreased affinity for FVIII	



VWD testing overview

Complete laboratory investigation begins with a comprehensive VWD testing panel

HemosIL liquid, ready-to-use assays help reduce errors and improve turnaround times

Diagnostic Guidelines

- Diagnosis requires several in-depth serological lab tests in conjunction with clinical criteria
- Lab testing should be guided by:
  - Clinical history
  - Physical findings prompting suspicion
  - Initial lab evaluation
- Labs should establish their own reference range

Classification and Typing

- Levels of VWF Antigen, VWF:RCo Activity, VWF:CB Activity and FVIII in patient sample determine VWD type and subtypes
- Subtypes must be confirmed using typing assays in conjunction with clinical criteria

Initial Tests for Investigation

- Routine and specialty tests for patients suspected of VWD include:
  - Routine screening (CBC and platelet counts, APTT, PT, Fibrinogen)4
  - VWD screening to aid in diagnosis (VWF:Ag, VWF:RCo, VWF:CB, Factor VIII)

Expected laboratory values in VWD*

	VWD Type 1	VWD Type 2			VWD Type 3	Normal
		2A&B	2M	2N		
VWF Antigen Levels	Below Normal Range	Low-Normal	Low-Normal	Normal	Very Low or Undetectable	Normal
VWF:RCo Activity	Below Normal Range	Below Normal Range	Below Normal Range	Normal	Very Low or Undetectable	Normal
VWF:RCo Activity/Antigen Ratio	> 0.6	< 0.6	< 0.6	> 0.6	N/A	> 0.6
VWF:CB Activity	Below Normal Range	Below Normal Range	Low-Normal	Normal	Very Low or Undetectable	Normal
VWF:CB Activity/ Antigen Ratio	> 0.6	< 0.6	> 0.6	> 0.6	N/A	> 0.6
FVIII Activity Levels	Low-Normal	Low-Normal	Low-Normal	Low and Ratio FVIII/ Ag < 0.7	Very Low	Normal

*VWD-suspected patients are typed based on Ag, Activity and FVIII levels.

High-performance fully automated chemiluminescence simplifies VWD investigation

Chemiluminescence and innovative recombinant technology

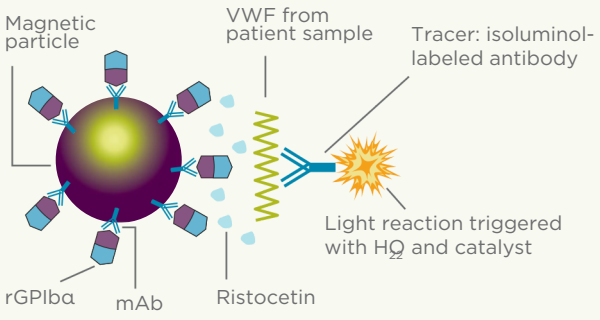
HemosIL AcuStar VWD Assay Panel

- Fully automated assays with no assay preparation
- No labor-intensive or manual methods required
- All assays feature reliable chemiluminescent technology with high analytical sensitivity for accurate results

HemosIL AcuStar VWF:RCo

Ristocetin-dependent chemiluminescent immunoassay

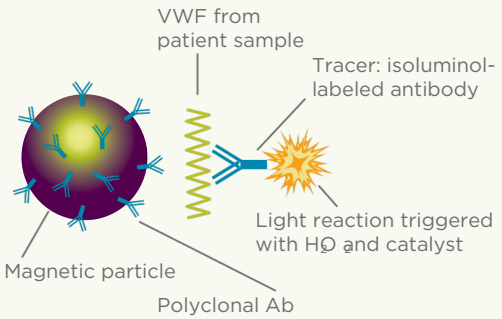
- Uses a recombinant fragment of the platelet receptor, glycoprotein Ib alpha (rGPIba), with VWF-binding sites, as a substitute for platelets
- In the presence of ristocetin, VWF in the sample binds to rGPIba proportionate to its ristocetin cofactor activity
- The isoluminol-labeled secondary antibody attaches to the captured VWF
- With the addition of triggers, light is emitted proportionate to the concentration of VWF activity in sample



HemosIL AcuStar VWF:Ag

Chemiluminescent immunoassay

- Uses magnetic particles coated with anti-VWF polyclonal antibodies
- VWF present in sample binds to magnetic particles proportionate to VWF antigen concentration
- Isoluminol-labeled VWF antibody attaches to captured VWF
- With the addition of triggers, light is emitted proportionate to the concentration of VWF antigen in the sample



NEW

HemosIL AcuStar VWF:CB

Chemiluminescent immunoassay

- Uses magnetic particles coated with a Type III collagen triple-helical peptide
- VWF present in sample binds to magnetic particles proportionate to its collagen-binding activity
- Isoluminol-labeled anti-VWF polyclonal antibody attaches to captured VWF
- When triggers are added, light is emitted proportionate to the concentration of VWF collagen-binding activity



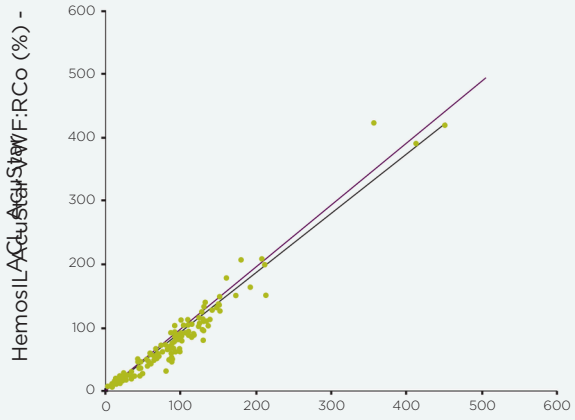
Broad working range for accurate VWD testing

Fully automated, innovative assay technology simplifies VWD testing

Excellent Correlation

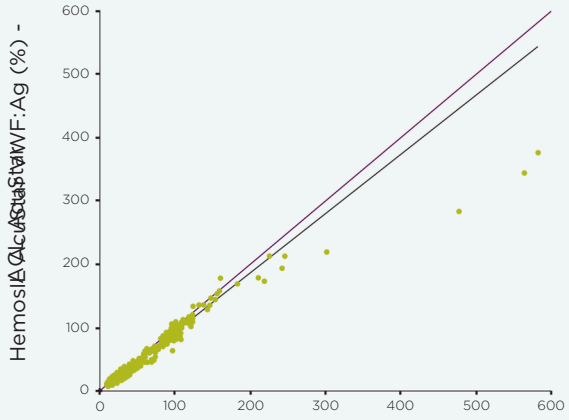
- Comparison studies were performed using normal and VWF samples covering the range of the assays
- HemosIL AcuStar VWF Assay Panel demonstrates excellent correlation with traditional methods

HemosIL AcuStar VWF:RCo vs. Platelet Aggregometry



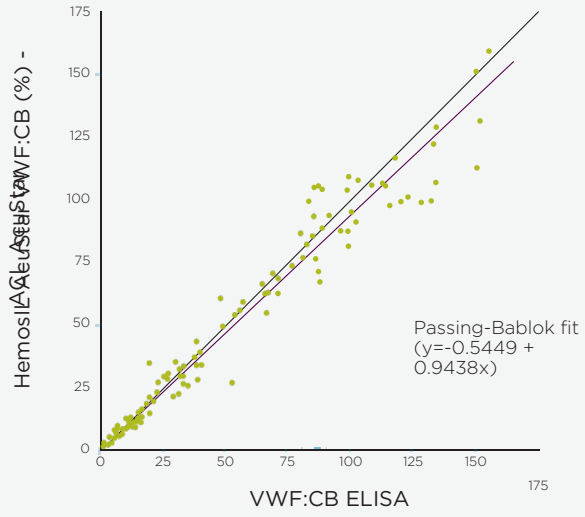
Sample size (n)	135
Slope	0.97
Correlation (r)	0.99

HemosIL AcuStar VWF:Ag vs. HemosIL VWF:Ag



Sample size (n)	127
Slope	0.93
Correlation (r)	0.99

HemosIL AcuStar VWF:CB vs. ELISA



Sample size (n)	139
Slope	0.9438
Correlation (r)	0.967



Enhanced analytical performance

Performance characteristics

		HemosIL AcuStar VWF:RCo		HemosIL AcuStar VWF:Ag		HemosIL AcuStar VWF:CB	
Precision		Low Control	Normal Control	Low Control	Normal Control	Low Control	Normal Control
Mean %		31.5	111.4	28.3	117.8	23.7	89
Total % CV		5.3	6.9	6.9	4.6	5.5	4.8
Within run % CV		3.5	4.2	5.9	3.2	5.2	3.6
Detection Limit (%)		0.17		0.13		0.2	
Working Range (%)							
Without rerun		0.5–200		0.3–400		0.5–200	
With rerun		0.5–4,000		0.3–8,000		0.5–1,347	
Onboard Stability (weeks)		8		8		5	
Interferences							
Hemoglobin (mg/dL)		500		500		500	
Bilirubin (mg/dL)		18		18		18	
Triglycerides (mg/dL)		1,250		1,250		1,250	
Rheumatoid Factor (IU/mL)		800		800		800	
Lower Limit of Normal Range	ABO	n = 287	45.6%	n = 287	52.2%	n = 261	50.50%
	O	n = 163	43.8%	n = 163	48.2%	n = 140	47.0%
	A+B+AB	n = 124	53.8%	n = 124	59.6%	n = 121	61.1%

HemosIL AcuStar VWD Assay Panel—a breakthrough for improved patient management and lab efficiency.

HemosIL AcuStar VWD Panel Kit Composition

Product	Part Number	Kit Configuration
HemosIL AcuStar VWF:RCo*	0009802024	1 Cartridge (25 tests) Calibrator 1, 1 x 1 mL (liq) Calibrator 2, 1 x 1 mL (lyo)
HemosIL AcuStar VWF:Ag*	0009802020	1 Cartridge (25 tests) Calibrator 1, 1 x 1 mL (liq) Calibrator 2, 1 x 1 mL (lyo)
NEW HemosIL AcuStar VWF:CB*	0009802044	1 Cartridge (25 tests) Calibrator 1, 1 x 1 mL (liq) Calibrator 2, 1 x 1 mL (lyo)
HemosIL AcuStar VWF Controls*	0009802119	Low VWF Control, 3 x 1 mL (lyo) Normal VWF Control, 3 x 1 mL (lyo)

*Not currently 510(k) cleared.

References

1. Laffan MA, *et al.* The diagnosis and management of von Willebrand disease: a United Kingdom Haemophilia Centre Doctors Organization guideline approved by the British Committee for Standards in Haematology. *Br J Haematol.* 2014;167(4):453–65.
2. National Hemophilia Foundation.
3. Diseases and Conditions Index: U.S. Department of Health and Human Services; National Institutes of Health; National Heart, Lung, and Blood Institute.
4. The Diagnosis, Evaluation, and Management of von Willebrand Disease. U.S. Department of Health and Human Services; National Institutes of Health; National Heart, Lung, and Blood Institute.

Additional Literature

Cabrera N, *et al.* Comparison of a new chemiluminescent immunoassay for von Willebrand factor activity with the ristocetin cofactor-induced platelet agglutination method. *Haemophilia.* 2013 Nov;19(6):920–5.

Caron C, *et al.* Measurement of von Willebrand factor binding to a recombinant fragment of glycoprotein Ibalpha in an enzyme-linked immunosorbent assay-based method: performances in patients with type 2B von Willebrand disease. *Br J Haematol.* 2006 Jun;133(6):655–63.

Favaloro EJ, Mohammed S. Evaluation of a von Willebrand factor three test panel and chemiluminescent-based assay system for identification of, and therapy monitoring in, von Willebrand disease. *Thromb Res.* 2016 May;141:202–11.

Freidman K, *et al.* A new chemiluminescent panel for the determination of VWF ristocetin cofactor and VWF antigen. Poster presented at 2012 58th Annual SSC Meeting Liverpool, England.

Stufano F, *et al.* A two-centre comparative evaluation of new automated assays for von Willebrand factor ristocetin cofactor activity and antigen. *Haemophilia.* 2014 Jan;20(1):147–53.

Vanhoorelbeke K, *et al.* A reliable and reproducible ELISA method to measure ristocetin cofactor activity of von Willebrand factor. *Thromb Haemost.* 2000 Jan;83(1):107–13.

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