## VWD Panel Kit Composition

| Product | Part Number | Kit Configuration |
|---|---|---|
| **HemosIL VWF:Ag (Latex)** | 0020002300 | Latex 2 x 3 mL (liq)<br>Buffer 2 x 4 mL (liq) |
| **HemosIL VWF Activity (Latex)** | 0020004700 | Latex 2 x 4.5 mL (lyo)<br>Buffer 2 x 4.5 mL (liq) |
| **HemosIL VWF:RCo* (Latex)** | 0020300900 | Latex 2 x 2 mL (liq)<br>Ristocetin 2 x 1.6 mL (liq)<br>Diluent 2 x 3.6 mL (liq)<br>Buffer 2 x 4 mL (liq) |
| **HemosIL FVIII Deficient Plasma** | 0020011800 | 10 x 1 mL (lyo) |
| **HemosIL FVIII Deficient Plasma (Normal VWF levels)** | 0020012800 | 10 x 1 mL (lyo) |

*Not FDA 510(k)-cleared; not available in all countries.


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VWD.Bro EUROW Rev00 03.23


Hemostasis Innovation is Here.

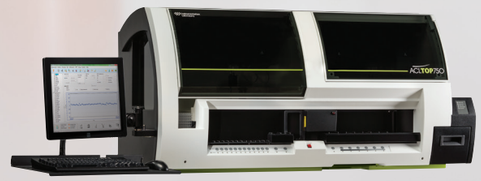
# HEMOSIL®
## VON WILLEBRAND DISEASE (VWD) ASSAY PANEL

# Simply complete.




- HemosIL VWF:Ag
- HemosIL VWF Activity
- HemosIL VWF:RCo
- HemosIL FVIII Deficient Plasma

Fully automated on the
ACL TOP® Family and ACL TOP Family 50
Series of Hemostasis testing systems



# A fully automated and complete panel of assays for VWD

VWD testing demands speed, accuracy, and efficiency. **HemosIL VWD assays** offer complete automated solutions for the investigation of VWD, contributing to accurate, timely diagnosis.



## Total solution for VWD investigation

- Comprehensive panel for VWD:
  - VWF Antigen
  - VWF Activity
  - VWF Ristocetin Cofactor Activity (VWF:RCo)*
  - Factor VIII*
- Meets current recommendations to measure platelet-binding activity of VWF (e.g. VWF:GPIbR) over traditional VWF ristocetin cofactor assays[1]

## Simple and efficient

- Liquid, ready-to-use reagents**
- Fully automated on Werfen Hemostasis testing systems
- No complex manual processes or results interpretation required

## Unmatched analytical performance

- Platelet-free activity assays deliver accurate and precise results
- Excellent correlation with manual, platelet-based, and ELISA methods
- Excellent on-board stability

*HemosIL VWF:RCo is available on ACL TOP Family and ACL TOP Family 50 Series systems only. Not FDA 510(k)-cleared; not available in all countries.

**HemosIL FVIII Deficient Plasma and VWF:Activity are lyophilized.

# VWD overview

## VWD is an inherited or acquired bleeding disorder[2]

### Definitions

- Caused by a qualitative or quantitative defect of von Willebrand factor (VWF)
- Affects both genders

### Incidence/prevalence

- Occurs in 1/100–1,000 people
- Estimated 1% prevalence in worldwide population
- The most common inherited bleeding disorder

### Clinical events

- VWD is clinically characterized by mucocutaneous bleeding including epistaxis, easy bruising, heavy menstrual bleeding, prolonged bleeding for minor wounds or the oral cavity, in addition, to bleeding after dental procedures, surgery, and postpartum.
- Musculoskeletal bleeding may be present in the most severe cases.
- Acquired VWD can be associated with serious autoimmune problems (e.g., rheumatoid arthritis, systemic lupus erythematosus), certain types of kidney failure or malignancies, or may not be associated with an underlying cause.
- Mild-to-moderate Type 1 VWD may remain undiagnosed until surgery or serious injury because symptoms can be mild.

## VWD classification[2,3]

Prompt diagnosis and classification optimize therapeutic management.

| Type | Phenotype |
|---|---|
| | **Quantitative deficiency of VWF** |
| 1 | Partial quantitative deficiency of VWF (~70–80% of confirmed cases) |
| 3 | Absence or near absence of VWF (<5% of confirmed cases and is the most severe) |
| | **Qualitative deficiency of VWF (~20% of confirmed cases)** |
| 2A | Decreased platelet-dependent function associated with loss of high molecular weight multimers (HMWM) |
| 2B | Increased binding to platelet GPIbα |
| 2M | Decreased platelet-dependent function with preserved multimer pattern |
| 2N | Decreased binding of FVIII |

# A total solution for accurate VWD testing

## Complete laboratory investigation begins with a comprehensive VWD testing panel

### Diagnostic guidelines

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

### Initial tests for investigation[1]

- Routine and specialty tests for VWD-suspected patients include:
  - Routine screening (CBC, Thrombin Time, APTT, PT, Fibrinogen)[1]
  - VWD screening to aid in diagnosis or exclusion (VWF:Ag, platelet-dependent VWF Activity, FVIII)

### Expected laboratory values in VWD[4]

| | VWD Type 1 | VWD Type 2 | | VWD Type 3 |
|---|---|---|---|---|
| | | 2A, 2B, 2M | 2N | |
| **VWF Antigen Levels** | Low | Low–Normal | Normal/Low | Undetectable |
| **VWF Activity** | Low | Very Low–Low | Normal/Low | Undetectable |
| **VWF Activity/ Antigen Ratio** | Normal | Low | Normal | N/A |
| **FVIII Activity Levels** | Normal/Low | Normal/Low | Very Low | Very Low |

## HemosIL VWD assay panel—complete and completely automated

HemosIL VWD assay panel offers a complete testing solution that meets guidelines on VWD investigation, including:[1]

| VWF:Ag | VWF Activity | VWF:RCo | FVIII |
|---|---|---|---|



# HemosIL VWF Activity assays

## Accurate, simple, and rapid platelet-dependent VWF activity assessment

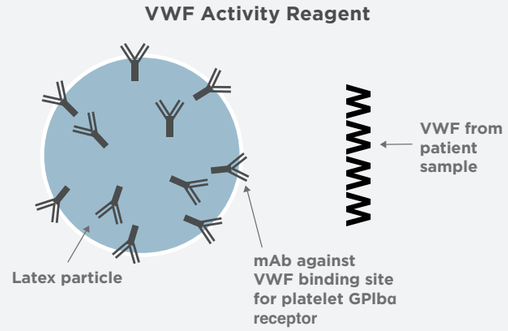
- Fully automated HemosIL VWF Activity and HemosIL VWF:RCo replace platelets and offer highly accurate results free of variability associated with human interpretation and assay preparation
- Both assays measure VWF functional activity and provide results with (VWF:RCo) or without (VWF Activity) ristocetin dependency

## VWF:Act (VWF:Ab)[5]

*Ristocetin-independent immunoturbidimetric assay*

### Principle

- Uses a specific mAb directed against VWF-binding site for platelet GPIbα receptor
- mAb-coated latex particles bind VWF if present in sample, resulting in agglutination

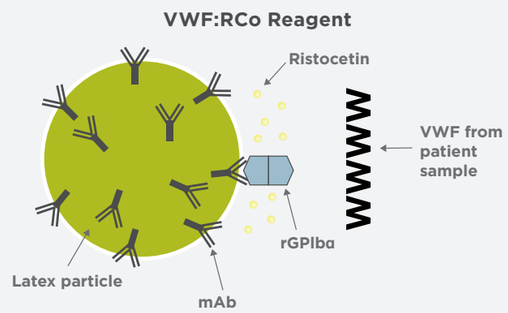



## VWF:RCo (VWF:GPIbR)[5]

*Ristocetin-dependent immunoturbidimetric assay*

### Principle

- Uses a recombinant fragment of the platelet glycoprotein-Ib alpha receptor (rGPIbα) containing VWF-binding site
- Recombinant fragment is a substitute for platelets
- Latex particles are coated with rGPIbα through a highly specific monoclonal antibody (mAb)
- If present in sample, VWF will bind to rGPIbα fragment in the presence of ristocetin
- Degree of agglutination is directly proportional to VWF activity in sample



# HemosIL VWF:RCo assay for comprehensive VWD investigation

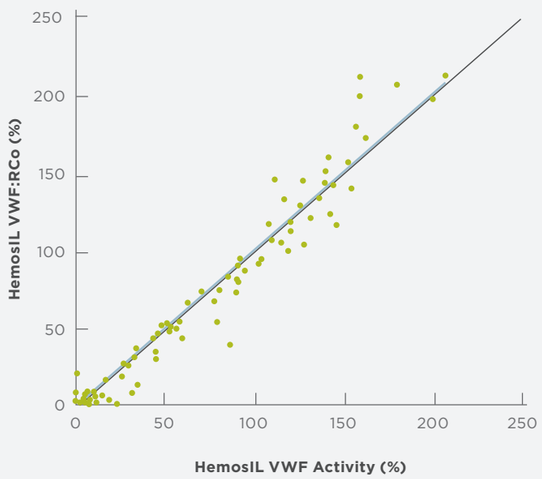
## Fully automated, innovative assay technology simplifies platelet-dependent VWF activity testing

**Excellent correlation**

Comparison studies were performed using samples covering the range of the assay. HemosIL VWF:RCo was compared to HemosIL VWF Activity on the ACL TOP Family and ACL TOP Family 50 Series systems and platelet aggregometry.

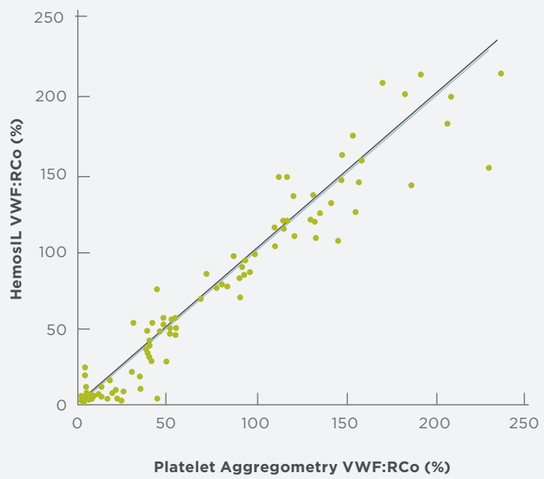
HemosIL VWF:RCo demonstrated excellent correlation with both assays.

**HemosIL VWF:RCo vs. HemosIL VWF Activity**




| | |
|---|---|
| Sample size (n) | 101 |
| Slope | 1.02 |
| Correlation (r) | 0.977 |

**HemosIL VWF:RCo vs. Platelet Aggregometry**




| | |
|---|---|
| Sample size (n) | 102 |
| Slope | 0.99 |
| Correlation (r) | 0.965 |

**HemosIL VWF:RCo also provides:**

- Superior accuracy and precision through platelet-free methodology
- High analytical sensitivity
- Platelet-binding technology, compliant with current guidelines[1]



# Excellent analytical performance on ACL TOP Family and ACL TOP Family 50 Series systems

## Performance characteristics

| | VWF:Ag | | VWF:Act | | VWF:RCo | |
|---|---|---|---|---|---|---|
| **Time-to-Results** | ~7 mins | | ~12 mins | | ~12 mins | |
| **Linearity Range (%)** | | | | | | |
| Without Rerun | 8.5–250 | | 19–130 | | 7–120 | |
| With Rerun | Up to 600 | | Up to 390 | | Up to 480 | |
| **Precision (%)** | **Mean** | **CV (Total)** | **Mean** | **CV (Total)** | **Mean** | **CV (Total)** |
| Normal Control | 107 | 3.2 | 102 | 3.4 | 112 | 5.5 |
| Special Test Level 1 | 80 | 3.7 | 68 | 6.3 | 72 | 6.9 |
| Special Test Level 2 | 36 | 4.6 | 30 | 8.0 | 26 | 6.8 |
| **Detection Limit (%)** | 2.2 | | 3.2 | | 4.4 | |
| **Inferences** *(None up to:)* | | | | | | |
| Hemoglobin | 120 mg/dL | | 70 mg/dL | | 500 mg/dL | |
| Bilirubin | 14 mg/dL | | 4.2 mg/dL | | 18 mg/dL | |
| Triglycerides | 1,500 mg/dL | | 1,020 mg/dL | | 1,300 mg/dL | |
| Rheumatoid Factor | 50 IU/mL | | 200 IU/mL | | May produce an overestimation | |
| **Normal Range %** | | | | | | |
| Blood Type O | 43–141 | | 40–126 | | 48–202 | |
| Blood-Types A, B, AB | 66–176 | | 49–163 | | 61–240 | |
| **Onboard Stability** | | | | | | |
| Continuous | 1 week at 15°C | | 5 weeks at 15°C | | 24 hours at 15°C | |
| Cumulative | | | | | 2 hrs/day, then 2–8°C for 10 hours over 11 days<br>4 hrs/day, then 2–8°C for 12 hours over 6 days | |

**HemosIL VWD assays on ACL TOP Family and ACL TOP Family 50 Series analyzers offer a complete, flexible, and fully automated solution.**