**von Willebrand Factor Activity - 0020004700**

**Intended use**
Autonomously enhanced immunosassay for the quantitative determination of von Willebrand Factor Activity (VWF Activity) in human citrated plasma on IL Coagulation Systems.

**Summary and principle**
The diagnosis of von Willebrand Disease (VWD), probably the most common congenital bleeding disorder, requires a number of special tests at the laboratory level. The measurement and comparison of von Willebrand Factor Antigen (VWF:Ag), VWF Activity and Factor VIII (VIII) levels in plasma aid in the differentiation of quantitative defects (type 1 or type 3) or qualitative defect (type 2) of VWF and therefore to diagnose the different types of VWD. 2,3 When an extremely low or undetectable level of VWF:Ag is obtained, a type 3 VWD could be expected. If a moderate or even normal result is obtained, VWF Activity and FVIII assays must be performed and compared with the VWF:Ag result. If all three values are within the normal range, VWD and Hemophilia A may be excluded. If at least one parameter is abnormally low, it is necessary to calculate the ratios VWF Activity/VWF:Ag and FVIII/VWF:Ag. If both ratios are close to 1 (0.7 ± cut-off), a VWD type 1 may be diagnosed. When the VWF:Activity/VWF:Ag ratio is low (0.7 is also the suggested cut-off), types 2A, 2B or 2M may be diagnosed. These subtypes are characterized by its abnormal multimeric pattern and/or its altered platelet affinity. 4,5 Additional laboratory tests as RIPA (Ristocetin Induced Platelet Aggregation), multimeric analysis and binding assays are required in order to be able to distinguish the different subtypes.6 When the FVIII/VWF:Ag ratio is low (0.7 is also the suggested cut-off), a type 2N or Hemophilia A may be diagnosed and a FVIII binding assay is necessary to discriminate among them. 7 The VWF Activity kit is a latex particle enhanced immunoturbidimetric assay to quantify VWF Activity of plasma. The activity of VWF is determined by measuring the increase of turbidity produced by the agglutination of the latex reagent. A specific anti-VWF monoclonal antibody adsorbed onto the latex reagent, directed against the platelet binding site of VWF (Glycoprotein Ib receptor), reacts with the VWF of patient plasma. The degree of agglutination is directly proportional to the activity of VWF in the sample and is determined by measuring the decrease of transmitted light caused by the aggregates.

**Composition**
The von Willebrand Factor Activity kit consists of:

- **Latex Reagent:** 2 vials x 4.5 mL of a lyophilized suspension of polystyrene latex particles coated with purified anti-VWF mouse monoclonal antibody directed against a functional epitope of VWF, containing bovine serum albumin, stabilizers and preservatives.
- **Buffer:** Cat. No. 0020004720: 2 vials x 4.5 mL of Tris buffer containing bovine serum albumin, stabilizers and preservatives.

**PRECAUTIONS AND WARNINGS:**
- Avoid contact with skin and eyes (S 24/25).
- Do not enter into drains (S 29).
- Wear suitable protective clothing (S 36).
- The buffer contains less than 0.1% sodium azide that may form explosive azides in metal plumbing. Use proper disposal procedures.

**Preparation**
- **Buffer:** The reagent is ready for use.
- **Latex Reagent:** Dissolve the contents of each vial by pouring the entire contents of one vial of Buffer into one vial of Latex Reagent. Replace the stopper and swirl to mix before use. Do not shake.
- Note: Avoid foam formation when homogenizing reconstituted reagents. Bubbles on top of the liquids may interfere with the instruments liquid sensors.

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**Reagent storage and stability**
Unopened reagents are stable until the expiration date shown on the vial when stored at 2–8°C.

**Latex Reagent:** Stability after reconstitution: 1 month at 2–8°C in the original vial. 3 days at 15°C on the ACL® 8000/9000/10000, 1 day at 15°C on the ACL Futura®/ACL Advance Systems or 5 days at 15°C on the ACL TOP.® Do not freeze.

For optimal stability remove reagents from the system and store them at 2–8°C in the original vial.

**Instrument/test procedures**
Refer to the appropriate IL instrument's Operator's Manual and/or Application Manual for the complete assay procedure instructions.

**Specimen collection and preparation**
- Nine parts of freshly drawn venous blood are collected into one part of trisodium citrate.
- Refer to NCCLS Document H21-A4 for further instructions on specimen collection, handling, and storage.8 Frozen plasma samples should be thawed at 37°C while gently mixing before testing. After thawing the assay must be performed within 2 hours.

**Additional reagents and control plasmas**
The following are not supplied with the kit and must be purchased separately.

**Special Test Control**
- **Special Test Control Level 1:** 68.4 4.8
- **Special Test Control Level 2:** 36.6 6.5

**Quality control**
- **Normal Control:** 92.1 4.1
- **Special Test Control Level 1:** 64.1 4.8
- **Special Test Control Level 2:** 30.3 6.5

**Correlation:**
- **System:** Slope Intercept r Comparative method
- **ACLS 8000/9000/10000** 0.832 4.782 0.972 VWF Activity EIA
- **ACL Futura/ACL Advance** 0.954 3.854 0.958 VWF Activity EIA
- **ACL TOP** 0.988 3.298 0.995 VWF Activity on ACL Advance

**Performance characteristics**
- **Precision:** Within run and total (run to run and day to day) precision was assessed over multiple runs.
- **VWF Activity results on ACL TOP are not affected by bilirubin up to 350% on ACL Futura/ACL Advance and up to 200% on ACL 8000/9000/10000. The assay does not show prozone effect (i.e. antigen excess) up to 700% on ACL Futura/ACL Advance or 1:10 with Factor diluent (50 µL of sample + 450 µL of Factor diluent) on the ACL TOP and reassayed in the standard test. The printed results must be multiplied by 4 or 10 to correct for the dilution.**

**Expected values**
A normal range study was performed using the VWF Activity kit.

**Blood ABO Type**

<table>
<thead>
<tr>
<th>Blood</th>
<th>ACL 8000/9000/10000</th>
<th>ACL Futura/ACL Advance</th>
</tr>
</thead>
<tbody>
<tr>
<td>O</td>
<td>122 38.0 - 125.2 (VWF Activity)</td>
<td>120 40.8 - 138.8 (VWF Activity)</td>
</tr>
<tr>
<td>A + B</td>
<td>126 49.2 - 167.9 (VWF Activity)</td>
<td>123 58.1 - 175.5 (VWF Activity)</td>
</tr>
</tbody>
</table>

In a separate study using 266 individual blood bank donor samples, the following results were obtained:

**Note:** VWF is an acute-phase reactant and stress, pregnancy and other situations affect its plasma concentration and therefore it might be advisable to repeat the analysis from another batch sample.

Ranges were calculated as recommended by the International Federation of Clinical Chemistry (IFCC)9. These results were obtained using a specific lot of reagent. Due to many variables, which may affect results, each laboratory should establish its own VWF Activity normal range.
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Bibliography / Literatur / Bibliografia / Bibliographie / Bibliografia / Litteratur / Litteraturförteckning / Βιβλιογραφία


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IVD
In vitro diagnostic medical device
In-vitro Diagnostikum
Dispositif médical de diagnostic in vitro
Per uso diagnostic in vitro
Dispositivo médico para utilización en diagnóstico in vitro
In vitro diagnostic medical product
Προϊόν για διαγνωστική χρήση σε in vitro

LOT
Batch code
Chargen-Bezeichnung
Identificación número de lote
Désignation du lot
Numero del lote
Número de lote
Batch nr.
Tillverkningskod
Αρ. Παραγωγής

Use by
Verwendbar bis
Caducidad
Utilisable jusqu’à
Da utilizzare prima del
Data limite de utilização
Användning
Χρήση έως

Temperature limitation
Festgelegte Temperatur
Temperatura de Almacenamiento
Températures limites de conservation
Limiti di temperatura
Limite de temperatura
Temperatur begränsningar
Temperatur gränser
Θερμοκρασία

Consult instructions for use
Belage beachten
Consultar la metodica
Lire le mode d’emploi
 Vedere istruzioni per l’uso
Consultar as instruções de utilização
Sa vejeldning for anvendelse
Ta del av instruksjonen før användning
Συμβουλές της οδηγίας χρήσης

CONTROL
Control
Kontrollen
Control
Contrôle
Controllo
Contrôle
Control
Kontroll
Δόση προετοιμασίας

Biological risks
Biologisches Risiko
Riesgo biológico
Risque biologique
Rischio biologico
Miljø oplysninger
Biologiska risker

Manufacturer
Hergestellt von
Fabricado por
Fabricant
Prodotto da
Fabricado por
Producent
Tillverkare

Authorised representative
Bevollmächtiger
Representante autorizado
Mandataire
Rappresentanza autorizzata
Representante autorizado
Leverander
Auktoriserad representant

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