### von Willebrand Factor Antigen (VWF:Ag) Determination

**Intended use**

Automated latex enhanced immunoassay for the quantitative determination of von Willebrand Factor Antigen (VWF:Ag) 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. Among them, VWF:Ag determination is essential and must be performed on every patient to reach a proper diagnosis. Depending upon these laboratory findings, VWD is classified into type 1 (the most frequent form being 70-80% of VWD), type 2 or type 3 (1 to 3% of VWD) groups. Type 1 shows a reduction of VWF although its structure and functionality is normal. In type 3, VWF is almost absent in plasma. In type 2 the quantity of VWF in plasma may be normal or slightly reduced but its molecular structure and its functionality is abnormal. Type 2 may be further characterized into subtypes by multimeric structure analysis of VWF. The VWF:Ag test is a latex particle enhanced immunoturbidimetric assay to quantify VWF:Ag in plasma. When a plasma containing VWF:Ag is mixed with the latex reagent and the Reaction Buffer included in the kit, the coated latex particles agglutinate. The degree of agglutination is directly proportional to the concentration of VWF:Ag in the sample and is determined by measuring the decrease of transmitted light caused by the aggregates.

**Composition**

The von Willebrand Factor Antigen Kit consists of:

- **Latex Reagent** (Cat. No. 0020002301): 2 vials x 3 mL of a suspension of polystyrene latex particles coated with a rabbit polyclonal antibody directed against VWF containing bovine serum albumin, buffer, stabilizer and preservative.
- **Reaction Buffer** (Cat. No. 0020002320): 2 vials x 4 mL of HEPES buffer containing bovine serum albumin, stabilizers and preservative.

**Precautions and Warnings:**

- Avoid contact with skin and eyes (S 24/25).
- Do not empty into drains (S 29).
- Wear suitable protective clothing (S 36).
- All reagents contain less than 0.1% sodium azide which may form explosive azides in metal plumbing. Use proper disposal procedures.

This product is For in vitro Diagnostic Use.

**Preparation**

Latex Reagent: Invert to mix before use.

Reaction Buffer: Invert to mix before use.

Note: Avoid foam formation when mixing reagents. Bubbles on top of the liquids may interfere with the instrument's liquid sensors.

**Reagent Storage and Stability**

Unopened reagents are stable until the expiration date shown on the vial when stored at 2-8°C. Opened reagents are stable 3 months at 2-8°C in the original vial or 1 week at 15°C on the ACL² 8000/9000/10000, ACL Futura³/ACL Advance Systems and ACL TOP,¹²,¹³ Do not freeze.

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

**Instrument/Tests procedures**

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

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**von Willebrand Factor Antigen**

**Specimen collection and preparation**

Nine parts of freshly drawn venous blood are collected into one part trisodium citrate (3.2%). Refer to NCCLS Document H21-A4 for further instructions on specimen collection, handling and storage. Thaw frozen specimens at room temperature for at least 15 minutes and centrifuge plasma 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.

<table>
<thead>
<tr>
<th>Country</th>
<th>VWF:Ag Cat. No.</th>
<th>VWF:Ag Cat. No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Americas</td>
<td>00020003000</td>
<td>0008467300</td>
</tr>
<tr>
<td>Pacific Rim</td>
<td>00020003120</td>
<td>0008467600</td>
</tr>
<tr>
<td>Europe</td>
<td>0009575900</td>
<td>0009575600</td>
</tr>
</tbody>
</table>

**Quality control**

Normal and abnormal controls are recommended for a complete quality control program. Normal Control, Special Test Control Levels 1 (that contains a level of VWF:Ag within the normal range) and Special Test Control Levels 2 (that contains a level of VWF:Ag within the abnormal range) are designed for this program. Each laboratory should establish its own mean and standard deviation and should establish a quality control program to monitor laboratory testing. Controls should be analyzed at least once every 8 hour shift in accordance with good laboratory practice. Refer to the instrument’s Operator’s Manual for additional information. Refer to Westgard et al for identification and resolution of out-of-control situations.

**Results**

VWF:Ag results are reported in % of normality. Refer to the instrument’s Operator’s Manual for additional information. The assay results should be used with other information, including the clinical context, in forming a diagnosis.

**Limitations/Interfering substances**

VWF:Ag results on ACL Futura/ACL Advance Systems are not affected by hemoglobin up to 80 mg/dL, bilirubin up to 10 mg/dL and lipids up to 1000 mg/dL.

VWF:Ag results on ACL Family Systems are not affected by hemoglobin up to 90 mg/dL, bilirubin up to 15 mg/dL and lipids up to 750 mg/dL.

The presence of Rheumatoid Factor may produce an overestimation of the test result.

VWF:Ag results on ACL TOP are not affected by hemoglobin up to 120 mg/dL, bilirubin up to 14 mg/dL, triglycerides up to 1500 mg/dL and Rheumatoid Factor up to 750 IU/mL.

**Expected values**

A normal range study was performed using VWF:Ag kit on IL Coagulation Systems.

<table>
<thead>
<tr>
<th>Blood ABO Type</th>
<th>N</th>
<th>ACL Family (% VWF:Ag)</th>
<th>ACL Futura/ACL Advance (% VWF:Ag)</th>
</tr>
</thead>
<tbody>
<tr>
<td>O</td>
<td>58</td>
<td>41.1 - 125.9</td>
<td>40.6 - 122.0</td>
</tr>
<tr>
<td>A + B + AB</td>
<td>56</td>
<td>61.3 - 157.8</td>
<td>61.3 - 152.6</td>
</tr>
</tbody>
</table>

These results were obtained using several lots of reagents. Ranges (mean ± 2SD) were estimated testing plasma samplesXGQ-healthy adult blood donor banks.

In a separate study using 252 individual blood bank donor samples, the following results were obtained:

<table>
<thead>
<tr>
<th>Blood ABO Type</th>
<th>N</th>
<th>ACL TOP (% VWF:Ag)</th>
</tr>
</thead>
<tbody>
<tr>
<td>O</td>
<td>126</td>
<td>42.0 - 140.8</td>
</tr>
<tr>
<td>A + B + AB</td>
<td>126</td>
<td>66.1 - 176.3</td>
</tr>
</tbody>
</table>

**Performance characteristics**

Within run and total (run to run and day to day) precision was assessed over multiple runs.

<table>
<thead>
<tr>
<th>System</th>
<th>Mean (% VWF:Ag)</th>
<th>CV% (Within run)</th>
<th>CV% (Total)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal Control</td>
<td>100.5</td>
<td>1.3</td>
<td>1.6</td>
</tr>
<tr>
<td>Special Test Controls Level 1</td>
<td>80.8</td>
<td>2.2</td>
<td>2.2</td>
</tr>
<tr>
<td>Special Test Controls Level 2</td>
<td>33.7</td>
<td>2.2</td>
<td>3.9</td>
</tr>
</tbody>
</table>

**ACL Futura**

<table>
<thead>
<tr>
<th>System</th>
<th>Mean (% VWF:Ag)</th>
<th>CV% (Within run)</th>
<th>CV% (Total)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal Control</td>
<td>107.5</td>
<td>3.0</td>
<td>3.2</td>
</tr>
<tr>
<td>Special Test Controls Level 1</td>
<td>79.5</td>
<td>2.5</td>
<td>3.7</td>
</tr>
<tr>
<td>Special Test Controls Level 2</td>
<td>35.5</td>
<td>3.2</td>
<td>4.6</td>
</tr>
</tbody>
</table>

**ACL TOP**

<table>
<thead>
<tr>
<th>System</th>
<th>Mean (% VWF:Ag)</th>
<th>CV% (Within run)</th>
<th>CV% (Total)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal Control</td>
<td>123.5</td>
<td>2.5</td>
<td>3.0</td>
</tr>
<tr>
<td>Special Test Controls Level 1</td>
<td>68.1</td>
<td>2.9</td>
<td>4.2</td>
</tr>
<tr>
<td>Special Test Controls Level 2</td>
<td>32.9</td>
<td>4.7</td>
<td>5.7</td>
</tr>
</tbody>
</table>

**Correlation**

<table>
<thead>
<tr>
<th>System</th>
<th>slope</th>
<th>intercept</th>
<th>r</th>
<th>Comparative method</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACL Family</td>
<td>1.00</td>
<td>-2.2</td>
<td>0.996</td>
<td>VWF:Ag EIA</td>
</tr>
<tr>
<td>ACL Futura</td>
<td>1.03</td>
<td>-3.8</td>
<td>0.997</td>
<td>VWF:Ag EIA</td>
</tr>
<tr>
<td>ACL TOP</td>
<td>0.97</td>
<td>2.2</td>
<td>0.995</td>
<td>VWF:Ag on ACL Advance</td>
</tr>
</tbody>
</table>

The precision and correlation results were obtained using specific lots of reagents and controls.

**Detection limit**

- **System**
  - ACL Family and ACL Futura/ACL Advance 3.5 (% VWF:Ag)
  - ACL TOP 2.2 (% VWF:Ag)

**Linearity**

- **System**
  - ACL Family and ACL Futura/ACL Advance 10 - 150 (% VWF:Ag)
  - ACL TOP 8.5 - 250 (% VWF:Ag)

Without prozone effect up to 1600%.

If the linear range is exceeded samples should be diluted 1:4 with Factor diluent (100 µL of sample + 300 µL of Factor diluent) and reassayed. This procedure should be repeated if the result is again above 600% or 1000% depending on the instrument (dilution ratio 1:16). The printed results must be multiplied by 4 or 16 (depending upon the number of dilution steps performed) to correct for the dilution. Instruments with Auto Rerun capability perform the samples dilution and result correction automatically.

**Tests on the ACL Systems**

- **VWF:Ag** 50 tests (approx.)
- **Tests on the ACL Futura/ACL Advance Systems and ACL TOP** 60 tests (approx.)


**Symbols used / Verwendete Symbole / Símbolos utilizados / Symboles utilisés / Simboli impiegati / Símbolos utilizados / Anvendt e symboler / Använda Symboler**

**Bibliography / Literatur / Bibliografía / Bibliographie / Bibliografia / Bibliografia / Litteratur / Litteraturförteckning / Bibliografia**


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**IVD**

*In vitro* diagnostic medical device

*In-vitro* Diagnostikum

*De uso diagnóstico in vitro*

*Dispositif médical de diagnostic in vitro*

*Per uso diagnostico in vitro*

*Dispositivo médico para utilización en diagnóstico in vitro*

*"In vitro" diagnostisk utstyr*

*In vitro* diagnostisk medicinsk produkt

*In vitro*

Производ для диагностики

**LOT**

Batch code

Chargen-Bezeichnung

Identificación número de lote

Désignation du lot

Numero del lote

Batch nr.

Titelverkningskod

Αρ. Παρτίδας

Χρήση εύς

**Use by**

Verwendbar bis

Caducidad

Utilizable jusqu’a

Da utilizzar prima del

Data limite de utilização

Användelse

Användning

**Temperature limitation**

Festgelegte Temperatur

Temperatura de Almacenamiento

Temperatures limites de conservation

Limiti di temperatura

Límite de temperatura

Temperatur begrænsninger

Temperatur gränser

**Consult instructions for use**

Beilage beachten

Consultar la metódica

Lire le mode d’emploi

Vedere istruzioni per l’uso

Consultar as instruções de utilização

Se vejledning for anvendelse

Ta del av instruktionen före användning

**CONTROL**

Control

Kontrollen

Contrôle

Controllo

Kontrol

**Biological risks**

Biologisch Risiko

Riesgo biológico

Risque biologique

Rischio biologico

Risco biológico

Biologisk risker

**Manufacturer**

Hergestellt von

Fabricado por

Fabricant

Produkto da

Fabricado por

Producent

Tilverkare

**Authorized representative**

Bevollmächtigter

Representante autorizado

Mandataire

Rappresentanza autorizzata

Representante autorizado

Leverandør

Auktoriserad representant

**REp**

EC

Eξωχώριστος εντομόσαρης

**Authorised representative**

Bevollmächtigter

Representante autorizado

Mandataire

Rappresentanza autorizzata

Representante autorizado

Leverandør

Auktoriserad representant