von Willebrand Factor Antigen - 0020002300

ENGLISH - Insert revision 07/2004

CE

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.[1] Among them, VWF:Ag determination is essential and must be performed on every patient to reach a proper diagnosis.[1]
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.[2,3] 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.
Apart from the above described inherited VWD, acquired VWD due to autoantibodies or to various disease states resulting in low rates of VWF synthesis has been reported. On the other side, chronic or acute inflammatory diseases or processes involving damage of the vascular endothelium yield abnormally high concentrations of VWF.[4]
The VWF:Ag kit 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.[5]

Composition

The **von Willebrand Factor Antigen** kit consists of:

R **Latex Reagent** (Cat. No. 0020002310): 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.

B **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 that 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 instruments 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 ACL® 8000/9000/10000, ACL Futura®/ACL Advance Systems and 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 trisodium citrate (3.2%). Refer to NCCLS Document H21-A4 for further instructions on specimen collection, handling and storage.[6] Thaw frozen specimens at 37°C 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.

	Americas and Pacific Rim Cat. No.	Europe Cat. No.
Calibration plasma	0020000000	0008467300
Normal Control	0020003120	0020003110
Special Test Controls Levels 1 & 2	0008467600	0008467600
Factor diluent	0009757600	0009757600

Quality control

Normal and abnormal controls are recommended for a complete quality control program.[7] Normal Control, Special Test Controls Level 1 (that contains a level of VWF:Ag within the normal range) and Special Test Controls Level 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.[8]

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.

Blood ABO Type[9]	N	ACL Family (% VWF:Ag)	ACL Futura/ACL Advance (% VWF:Ag)
O	58	41.1 - 125.9	40.6 - 122.0
A + B + AB	56	61.3 - 157.8	61.3 - 152.6

These results were obtained using several lots of reagents.
Ranges (mean ± 2SD) were estimated testing plasma samples8XgQ-healthy adult blood bank donors.

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

Blood ABO Type[9]	N	ACL TOP (% VWF:Ag)
O	126	42.0 - 140.8
A + B + AB	126	66.1 - 176.3

Ranges were calculated as recommended by the International Federation of Clinical Chemistry (IFCC).[10] 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:Ag normal range.

Performance characteristics

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

ACL Family	Mean (% VWF:Ag)	CV% (Within run)	CV% (Total)
Normal Control	105.0	1.3	1.6
Special Test Controls Level 1	80.8	1.3	2.2
Special Test Controls Level 2	33.7	2.2	3.9
ACL Futura ACL Advance	**Mean (%VWF:Ag)**	**CV% (Within run)**	**CV% (Total)**
Normal Control	107.0	3.0	3.2
Special Test Controls Level 1	79.5	2.5	3.7
Special Test Controls Level 2	35.5	3.2	4.6
ACL TOP	**Mean (%VWF:Ag)**	**CV% (Within run)**	**CV% (Total)**
Normal Control	123.5	2.0	3.0
Special Test Controls Level 1	68.1	2.9	4.2
Special Test Controls Level 2	32.9	4.7	5.7

Correlation:

System	slope	intercept	r	Comparative method
ACL Family	1.00	-2.2	0.996	VWF:Ag EIA
ACL Futura ACL Advance	1.03	-3.8	0.997	VWF:Ag EIA
ACL TOP	0.97	2.2	0.995	VWF:Ag on ACL Advance

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

VWF:Ag	60 tests (approx.)

Instrumentation Laboratory

Instrumentation Laboratory Company - Lexington, MA 02421-3125 (USA)
Instrumentation Laboratory SpA - V.le Monza 338 - 20128 Milano (Italy) EC REP

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Symbols used / Verwendete Symbole / Símbolos utilizados / Symboles utilisés / Simboli impiegati / Símbolos utilizados / Anvendte symboler / Använda Symboler / Χρησιμοποιηθέντα σύμβολα

In vitro diagnostic medical device
In-vitro Diagnostikum
De uso diagnóstico *in vitro*
Dispositif mèdical de diagnostic *in vitro*
Per uso diagnostico *in vitro*
Dispositivo médico para utilização em diagnóstico *in vitro*
"in vitro" diagnostisk udstyr
In vitro diagnostisk medicinsk produkt

In vitro

Προϊόν για διαγνωστική χρήση

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

Αρ. Παρτίδας

Use by
Verwendbar bis
Caducidad
Utilisable jusqu'à
Da utilizzare prima del
Data límite de utilização
Anvendelse
Användning

Χρήση έως

Temperature limitation
Festgelegte Temperatur
Temperatura de Almacenamiento
Températures limites de conservation
Limiti di temperatura
Límite de temperatura
Temperatur begrænsninger
Temperatur gräns

Περιορισμοί θερμοκρασίας

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

Συμβουλευτήτε τις οδηγίες χρήσης

Control
Kontrollen
Control
Contrôle
Controllo
Controlo
Kontrol
Kontroll

Υλικό ποιοτικού ελέγχου

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

Βιολογικοί κίνδυνοι

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

Κατασκευαστής

Authorised representative
Bevollmächtigter
Representante autorizado
Mandataire
Rappresentanza autorizzata
Representante autorizado
Leverandør
Auktoriserad representant

Εξουσιοδοτημένος αντιπρόσωπος