Technical File

LIAPHEN™ vWF:Ag

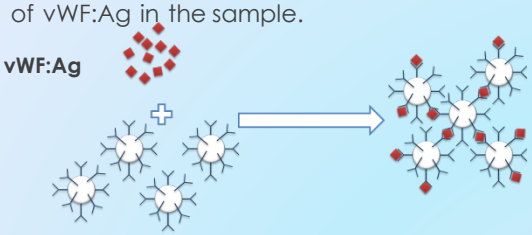
Product Ref. N°	A120206-RUO
Kit presentation	Ready to use Latex automated method, R1. Reactive Buffer; R2: Latex
Status	RUO

Intended use:

Latex automated Immunoturbidimetric assay for measuring of von Willebrand Factor Antigen (vWF:Ag) in human citrated plasma.

Assay principle:

Immunoturbidimetric method, based on antigen-antibody reaction. The absorbance change is directly proportional to the amount of vWF:Ag in the sample.



Latex particles with rabbit anti-vWF polyclonal Abs

vWF:Ag in practice:

- **RUO Applications:**
  - For use in vWF research laboratories
  - vWF functional or quantitative deficiency leads to von Willebrand disease (vWD) characterized by abnormal vWF adhesion activity.
  - vWF deficiencies can develop in association with other pathologies, thus constituting an acquired von Willebrand disease.
  - When vascular endothelium is affected, the vWF concentration can be increased in relation to inflammatory processes.
  - Recent studies showed that very high vWF concentrations correlate with organ failure, liver disease severity, and might predict in-hospital survival in acute-on-chronic liver failure patients
- **Market requirements & challenges:**

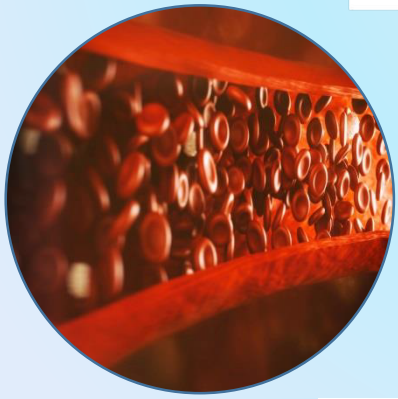
✓ Rapid and performing vWF:Ag automated assay, highly stable, polyvalent for use on major automated coagulation analyzers. An extended dynamic range is of high value for the identification of vWD (low range) as well as for high to very high vWF concentrations

Key Characteristics & Advantages:

Easy and fast Automation:
- Simple, rapid (<5min), fully automatable on any coagulati n analyzer.
- Method applicati ns: Sysmex CS-series, STA-R® series , ACL TOP® family and BCS® XP.

OPTIMIZE YOUR ASSAY!

Optimized consumption with extended stability compared to other assays
- 15 days onboard (CS-series and STA-R®)
- Long shelf life at 2-8°C in original packaging



Extended measurement range (3-1600% vWF:Ag) useful to explore various contexts

No hook effect up to 1600%

An bodies specific of vWF:Ag

Excellent Precision with very low CVs:
- Within-run < 4.6 % (example, STA-R and CS-5100)
- Between-run < 3.6% (example, STA-R and CS-5100)

Specific reliable assay, without interferences related to usual sample content (Hemoglobin, bilirubin, triglycerides, heparins and DOACs)

Standardized method for optimal routine testing
- Improved lot-to-lot variability; High quality raw materials used
- Calibrators/controls traceable to WHO International Standard

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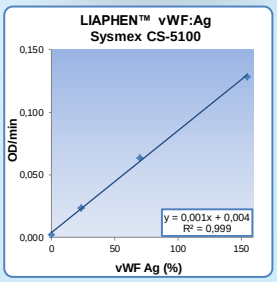
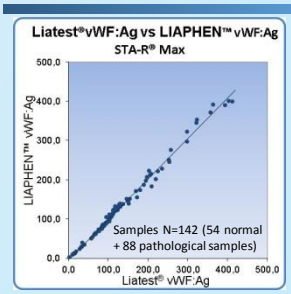
Assay Characteristics*: Multiplatform, easy to use, highly stable, low CVs , no interferences

Calibration curve:

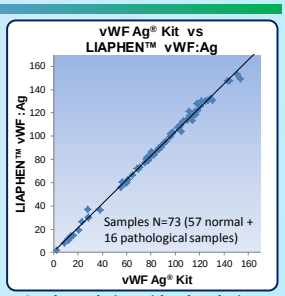


Measurement range: **3-1600%**
(automatic redilution > 150%)
Detection Limit: LLOD 0.7%
No hook effect: up to 1600%

Method Comparison (STA-R® and CS):

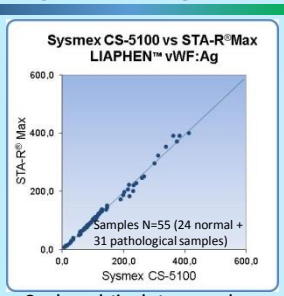


Good correlation with other device:
N=142
y =1.06x -3.9
r = 0.998



Good correlation with other device:
N=73
y = 1.03x+0.49
r = 0.998

Analyzers Comparison:



Good correlation between analyzers:
N=55
y = 1.07x-5.68
r = 0.996

Interferences and specificity:

High Specificity

- Polyclonal antibodies fully specific for vWF
- Expected normal concentrations: 62-169%
- Specificity verified on vWF deficient plasma: vWF:Ag %: < LOD

No interference of anticoagulant drugs

- Bias % was globally < 5% on controls (2IU/mL Heparins; 400ng/mL DOACs : Apixaban, Rivaroxaban, Dabigatran)

No interference of usual interferents and Plasma content

- Bias% was globally < 5% on controls (60 mg/dL Bilirubin, 1000mg/dL Hb or Intralipids)

Precision (CS-5100 / STA-R®):

Intra-series (N=40 determinations)

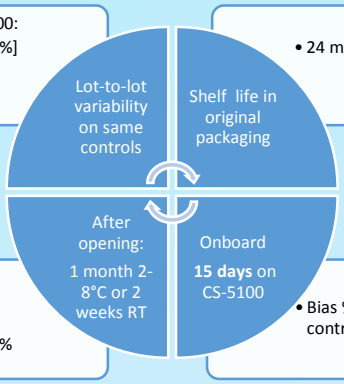
CS-5100	STA-R®
CV% 2.2% (vWF:Ag= 103%)	CV% 2.2% (vWF:Ag= 100%)
CV% 4.6% (vWF:Ag= 40%)	CV% 3.6% (vWF:Ag= 38%)

Inter-series (n=30 determinations, 5 days, 10 runs)

CS-5100	STA-R®
CV% 2.2% (vWF:Ag= 103%)	CV% 2.6% (vWF:Ag= 101%)
CV% 2.6% (vWF:Ag= 39%)	CV% 3.6% (vWF:Ag= 38%)

Example of stability and lot-to-lot variability:

- 3 lots on CS-5100:
- Normal [99-103%]
- Low [38-40%]



- 24 months at 2-8°C

- Fresh vs stored: Δ% (OD/min at ≈100%) was < 5% (on CS)
- Bias % was <5% on controls

Kit presentation:

R1: 4 x 5 mL
R2: 4 x 6 mL

* The values cited for the assay characteristics of the assay represent example of typical results and are not to be regarded as specifications for the test

Related products:

Needed	Product name	Ref N°:
Calibrator / Controls	BIOPHEN™ Plasma Calibrator BIOPHEN™ Normal Control Plasma BIOPHEN™ Abnormal Control Plasma	A222101 A223201 A223301
Buffer	Imidazole Buffer	AAR021A/K/L

For information	Product name	Ref N°:
ELISA	ZYMUTEST™ vWF	ARK030A-RUO
ELISA	ZYMUTEST™ vWF:CBA	ARK038A-RUO
Aggregometry	Ristocetin	AAG004K-RUO
Aggregometry	Lyophilized platelets	AAG006A or AAG006K

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