

LIAPHEN™ Free Protein S

Product Ref. N° A120004-RUO

Kit presentation Ready to use Latex automated method, R1: Reaction Buffer; R2: Latex

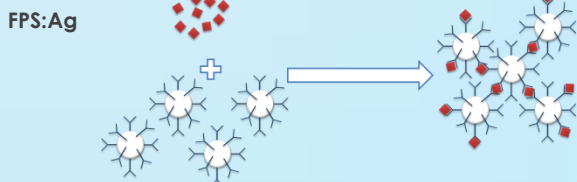
Status RUO

Intended use:

Latex automated Immunoturbidimetric assay for the quantitative determination of Free PS (FPS) Antigen (Ag) in human citrated plasma.

Assay principle:

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



Key Characteristics & Advantages:

Free Protein S in practice

Research Applications:

- Congenital or acquired PS deficiencies (associated with an increased risk of VTE).
- Research contexts with decreased PS: Early stages of inflammation in link with C4b-BP elevation; Dicumarol or L-asparaginase therapy; Oral contraceptives intake or oestrogen therapy; Pregnancy; Hepatic disorders; Nephrotic syndrome; DIC...

Market requirements & challenges:

- ✓ Highly standardized and performing, stable, Free PS assay with limited pre-analytical influences, polyvalent for use on major automated coagulation analyzers.
- ✓ Frequently used as the 1st intention assay for measurement of Free-PS (reflecting PS cofactor anticoagulant activity).

Innovative alternatives to support your needs

Easy and fast Automation:

- Simple, rapid (<5min), fully automatable on any coagulation analyzer.
- Method applications: Sysmex CS-series, STA-R® series, ACL-TOP® family and BCS® XP

IMPROVE YOUR ROUTINE!

Optimized consumption with extended stability compared to other assays

- 10 days onboard (CS),
- Long shelf life at 2-8°C in original packaging

Extended measurement range (6-300% Free PS) useful to explore various contexts

No hook effect up to 600%
High specificity for Free PS

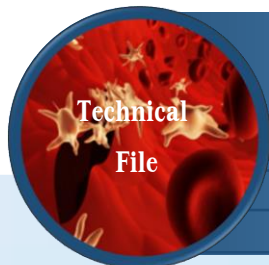
Excellent Precision with very low CVs:

- Within-run < 2.5% (example of CS-5100)
- Between-run < 1.9% (example of CS-5100)

Specific and reliable assay, without interferences related to sample content (Hemoglobin, bilirubin, triglycerides, heparins, DOACs, high Fibrinogen, high platelet count, presence of Rheumatoid Factor (up to 3,000 IU/mL)

Safe and standardized method for optimal routine testing

- Improved lot-to-lot variability; High quality raw materials used
- Calibrators/controls traceable to WHO International Standard



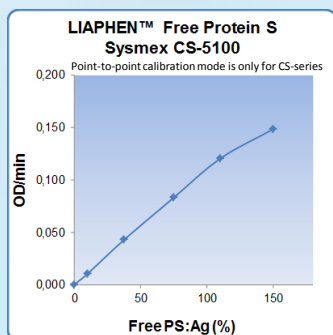
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Assay Characteristics*:

Multiplatform, easy to use, highly stable, low CVs , no interferences

Calibration curve & measurement range:

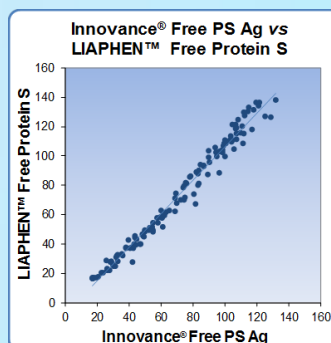


Measurement range:
6-300%
(automatic redilution
> 145%)

Detection Limit:
LLOD <0.6%

No hook effect:
up to 600%

Method Comparison (CS-5100):



Samples N=131:
69 normal samples
62 pathological samples:
patients with PS
deficiency, patients with
VKA treatment and diluted
normal samples.

**Good correlation with the
other device:**

$y = 1.14x - 7.98$
 $r = 0.990$ $P < 0.0001$

Interferences and specificity:

High Specificity

- MoAbs pair fully specific for Free PS
- Expected normal concentrations: 60-137%
- Specificity verified on PS immunodepleted plasma: PS % < LOD
- Inhibition of PS reactivity through addition of C4b-BP

No interference of anticoagulant drugs

- Bias % was globally < 5% on controls (10IU/mL Heparins; 400ng/mL DOACs : Apixaban, Edoxaban, 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, 12g/L Fbg, 490.10⁹/L Platelets, 3000IU/mL Rheumatoid Factor)

Intra-series

- **N=40 determinations**
- **CV% 2.5% (FPS= 98%)**
- **CV% 1.8% (FPS= 29%)**

Inter-series

- **n=30 determinations (5 days, 10 runs)**
- **CV% 1.2% (FPS= 95%)**
- **CV% 1.9% (FPS= 30%)**

Example of stability and lot-to-lot variability:

- 3 lots on CS-5100:
- Normal [93-94%]
- Middle [57-59%]
- Low 31%

Lot-to-lot
variability
on same
controls

Shelf life in
original
packaging

- 18 months at 2-8°C

After
opening:
4 months 2-
8°C or 2
weeks RT

Onboard
10 days on
CS-5100

- Bias % was <3% on controls

- Fresh vs stored:
 $\Delta\%$ (OD/min at
150%) was < 3%
(on CS)

Kit presentation:



* The values cited for the performance 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°:
Clotting	HEMOCLOT™ Protein S	ACK041K-RUO
ELISA	ZYMUTEST™ Free PS	ARK015B-RUO-MIN
ELISA	ZYMUTEST™ Total PS	ARK021A-RUO

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