



Please note that the uses described in the following page(s) have not been approved or cleared by FDA, with respect to the described assay or test.

In the US, the product is intended **For Research Use Only.**
Not for Use in Diagnostic Procedures.

Intended use and applications

IVD: CE 510(k) RUO

Assay of Anti-B2GPI antibodies of the IgG or IgM isotype in recurrent unexplained miscarriage, unexplained lupus anticoagulant, without or with thrombosis, Anti-phospholipid syndrome (APS), ... contexts.

Principle

Assay of anti-B2GPI antibodies, IgG or IgM isotype, by ELISA, in citrate or Na2EDTA anticoagulated plasma or serum.

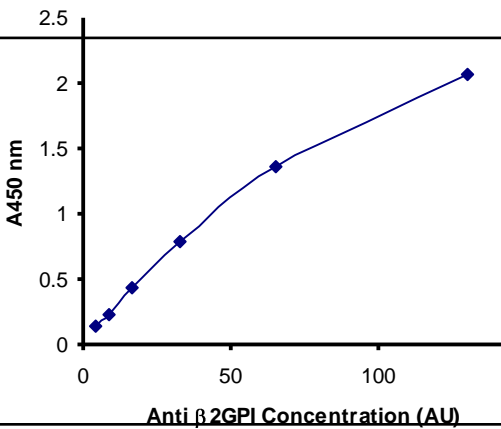
Complete disposable kit of 96 wells (12x8), including calibration and control system.

Defined antiB2GPI concentrations (in arbitrary units AU) are determined by reference to a normal population, and duly indicated for each lot.

Characteristics and advantages

- **Simple and rapid:** total assay time ~1h15 min; by manual method or on specific automates for ELISAs.
- **Optimized and highly specific** measurement of human AntiB2GPI antibodies of the IgG or IgM isotype, reactive with immobilised non denatured, fully active native human B2GPI, highly purified. Other isotypes are not measured.
- Includes **calibrators and controls:** traceable to an internal reference standard (concentration in AU), established by reference to a normal population: ensures **high reliability, high accuracy and reproducibility** from lot to lot, and run to run, for the cut-off.
- **Offers an optimised discrimination between normal individuals and pathologies with presence of AntiB2GPI antibodies.**
- Dynamic range **0 to > 50 AU/ml** (plasma dilution 1:100)
- Reproducibility: **2 to 7%**
- Detection limit **≤ 5 AU/ml**
- **Normal range (negative zone):** < 10 AU/ml
- **Grey zone (high background):** 10 to <20 AU/ml
- **Positive zone:** Low ≥ 20 to <50 AU/ml / Moderate ≥ 50 to <100 AU/ml / High > 100 AU/ml
- **High stability** (5 days to 4 weeks at 2-8 C).

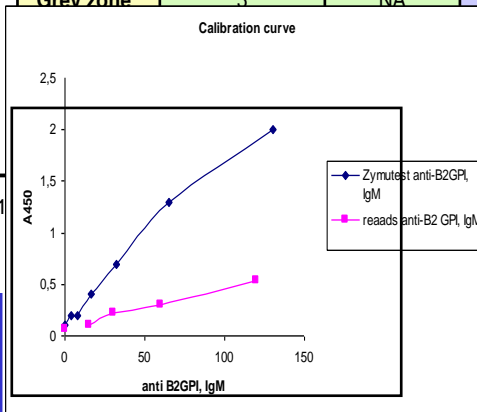
Calibration curve



Dynamic range: 0 to > 50 AU/ml for IgG or IgM.

Performance comparison with commercial devices

AntiB2GPI kits	IgG isotype		IgM isotype	
	ZYMUTEST (Hyphen)	REAADS (Corgenix)	ZYMUTEST (Hyphen)	REAADS (Corgenix)
N samples	38	38	38	38
Negative	31	35	27	29
Grey zone	3	NA	5	NA
			6	9



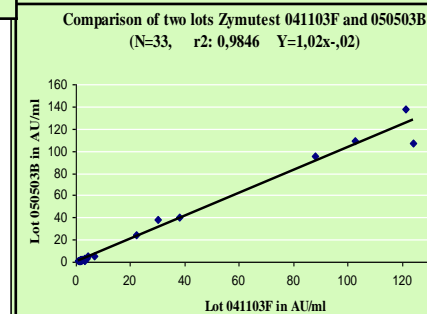
Conclusion: Results globally consistent for normal. The risk of rendering a "false negative" is with ZYMUTEST, as defining a "grey zone". Inconsistent results between kits are often related to reagent preparation (for antibodies capture), and differential used for the definition of the "zones".

Inter lots : example for IgG

N=39 samples*	Anti-B2GPI IgG	
	Lot 1	Lot 2
Negative	26	26
Grey zone	0	0
Low Positive	3	3
Moderate Pos	1	1
High Positive	9	9

Excellent correlation on the dynamic range from lot to lot.

(* 6 samples excluded: « high positivity » exceeding the upper limit of the dynamic range).



Related products

1. Zymutest anti B2GPI IgA (#ARK014C)
2. Zymutest ACA-APA, anti-Annexin V, anti PC, anti PS, anti PZ, anti Prothrombin,... IgG or IgM isotypes
3. Zymutest B2GPI (#ARK022A)
4. B2GPI (#APP010A)

References

- 1) Standardization of Immunoassays for Antiphospholipid Antibodies with β2GP1 and Role of Other Phospholipid Cofactors": Amiral J. et Al, Haemostasis, 1994:24, 191-203.
- 2) "Diagnostic Approach of Phospholipid –dependent Antibodies"; Amiral J., Haemostasis, 1999:29, 135-149.
- 3) "Variability of anti-B2GPI antibodies measurement by commercial assays"- A collaborative study in the frame of the European Forum on Antiphospholipid Antibodies Standardization Group, Reber G, Tincani A, Sanmarco M, de Moerloose P, Boffa MC, Thromb Haemost, 94:665-72, 2005.
- 4) W. Zammiti et al., Antibodies to b2-glycoprotein I and annexin V in women with early and late idiopathic recurrent spontaneous abortions, Arch Gynecol Obstet (2006) 274: 261–265

D.750.30/ZY/014 /1 (Aug2009)