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  S10(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 anti-B2GPI 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**

The Calibration curve illustrates the detection range of the kit, ensuring maximum sensitivity and accuracy.

**Performance comparison with commercial devices**

A comparison graph showing performance metrics against commercial devices similar to the Zymutest anti-B2GPI IgG/IgM kit. This includes data on reproducibility, dynamic range, and sensitivity.

**Inter lots: example for IgG**

A table illustrating the performance of the kit across different lots, with data on reproducibility and sensitivity. This table includes data from multiple lots and shows how consistent the performance is across different batches.

**References**

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)

**Related products**

- Zymutest ACA-APA, anti-Annexin V, anti PC, anti PS, anti PZ, anti Prothrombin...
- IgG or IgM isotypes
- Zymutest B2GPI (#ARK022A)
- B2GPI (#APP010A)

1) Standardization of Immunoassays for Antiphospholipid Antibodies with β2GPI and Role of Other Phospholipid Cofactors*: Amiral J. et Al, Haemostasis, 1994-24, 191-203.
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)