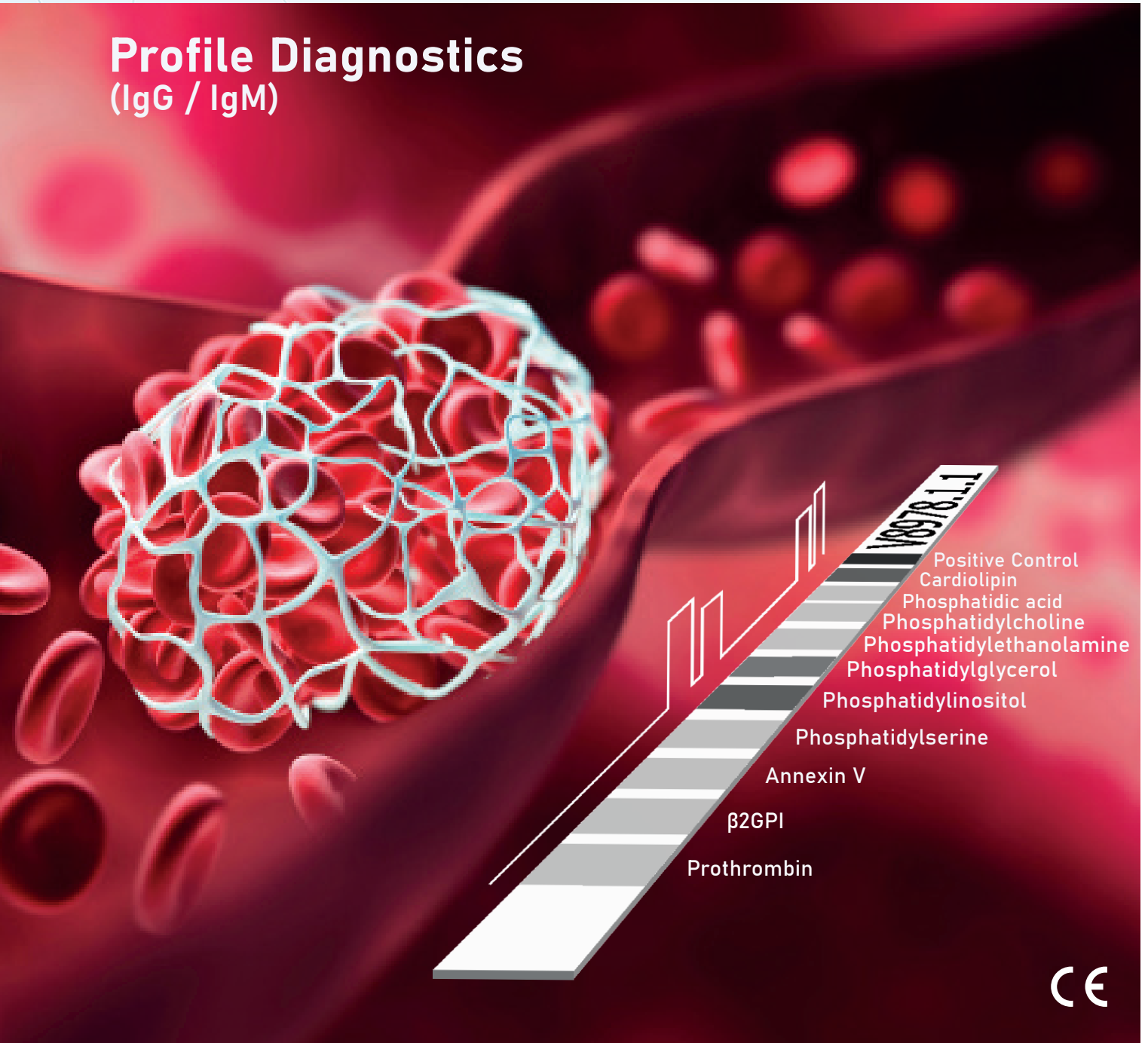


# Anti-Phospholipids

LINE Immunoassay for the determination of IgG or IgM antibodies to phospholipids and serum proteins in human serum



## Profile Diagnostics (IgG / IgM)



### Product Highlights

- Specific detection of IgG and IgM antibodies against phospholipids (aPL)
- Serological marker for antiphospholipid syndrome (APS)
- Excellent Simultaneous detection of 10 criteria and non-criteria aPL

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30 Years of Experience, 150 Partners in more than 100 Countries

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### Anti-Phospholipid Syndrome

Antiphospholipid syndrome (APS) is a chronic autoimmune disorder affecting approximately 1% of the population, either as a primary condition or in association with other autoimmune diseases. APS is characterized by recurrent thrombosis and/or pregnancy complications in the presence of antiphospholipid antibodies (aPL). Diagnosis relies on both clinical and laboratory criteria, with solid-phase assays detecting persistent aPL, including IgG and IgM to beta-2-glycoprotein I ( $\beta$ 2GPI), the cardiolipin (CL)- $\beta$ 2GPI complex and the lupus anticoagulants (LA) in clotting tests.

Despite advancements, aPL analysis faces challenges due to their diversity and test standardization issues. Recent research suggests that specific anti- $\beta$ 2GPI antibodies can differentiate between related and unrelated antibodies to APS. Various aPL positivity profiles, such as single, double, or triple positivity, help stratify risk in APS patients. Triple positivity correlates with higher clinical risk. Although LA positivity is a robust predictor, medium/high IgG levels to CL and  $\beta$ 2GPI are more indicative than IgM or low-level antibodies.

Although aPL are pathogenic, they typically require a "second hit" to trigger APS manifestation, which can be influenced by factors like cardiovascular risks, acquired thrombotic risks, genetic predispositions, and infections. The persistent presence of aPL in asymptomatic carriers raises questions about their pathogenic potential and the timing of the triggering event.

Advanced assay techniques, including LINE immunoassays (LIAs), offer improved detection and association with APS phenotype compared to traditional methods like an ELISA. LIAs, along with other novel approaches show promise in enhancing APS diagnosis and risk assessment.<sup>123</sup>

### Diagnostic Relevance

APS, an autoimmune disorder characterized by clinical symptoms such as thrombocytopenia, arterial (venous) thrombosis, and recurrent fetal loss, as well as systemic lupus erythematosus (SLE) is characterized by the presence of autoantibodies reactive to negatively charged phospholipids. In autoimmune patients, phospholipid antibodies seem to recognize phospholipids associated with plasma protein co-factors, e.g.  $\beta$ 2GPI, a serum protein with a molecular weight of ca. 50 kDa, that affects platelet aggregation and coagulation. Negatively charged phospholipids such as cardiolipin interact with the positively charged fifth domain of  $\beta$ 2GPI. This interaction that leads to conformational changes in the protein and the creation of new epitopes recognized by autoimmune phospholipid autoantibodies.

<sup>1</sup> Roggenbuck *et al.*, (2016) Antiphospholipid antibodies detected by line immunoassay differentiate among patients with antiphospholipid syndrome, with infections and asymptomatic carriers.

<sup>2</sup> Anunciación-Llunell *et al.*, (2022) Differences in Antiphospholipid Antibody Profile between Patients with Obstetric and Thrombotic Antiphospholipid Syndrome.

<sup>3</sup> Tkachenko *et al.*, (2020) Profiling of non-criteria antiphospholipid antibodies in patients with SLE: differentiation of thrombotic SLE patients and risk of recurrence of thrombosis.

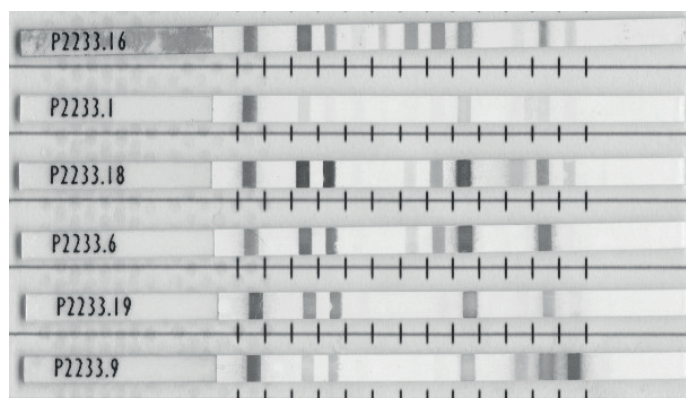
# Anti-Phospholipids

## LINE Immunoassays (LIA) for the diagnostic of antiphospholipid syndrome

### Anti-Phospholipid Assays

The LINE Immunoassay (LIA) represents a significant advancement in diagnosing antiphospholipid syndrome (APS). This innovative technique allows for the simultaneous detection of up to 10 antibodies targeting phospholipids and serum proteins in a single comprehensive assay, streamlining the evaluation process.

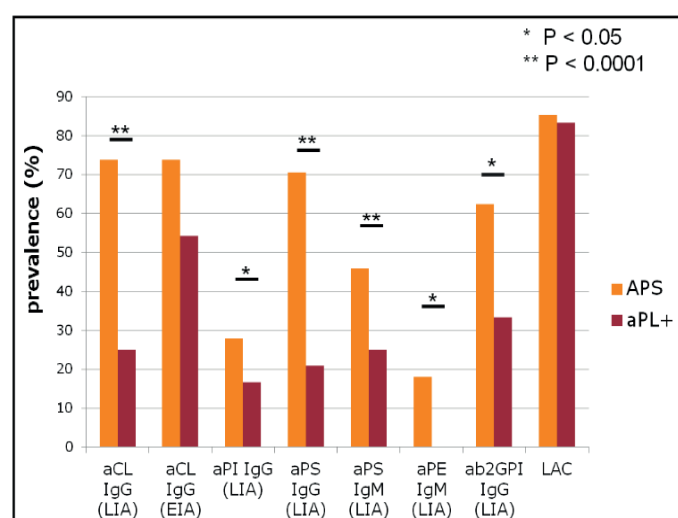
One of the key advantages of LIA is its heightened sensitivity, achieved through optimal epitope presentation on a hydrophobic membrane. This results in a stronger correlation between anti-phospholipid antibodies detected via LIA and the presence of APS, covering both general symptoms and specific complications such as recurrent miscarriages or cerebrovascular events associated with the syndrome. Additionally, LIA demonstrates reduced reactivity to transient antibodies, particularly those produced during infectious diseases.



Profiles of antibodies against phospholipids and serum proteins of various APS patients in the anti-phospholipid 10 Dot.

during infectious diseases. This characteristic decreases the likelihood of false positives, ensuring greater precision in APS diagnosis and monitoring. LIA offers a cost-effective approach to APS diagnostics by simplifying the procedure and requiring fewer determinations compared to traditional ELISA methods. This improved efficiency translates into cost savings for healthcare providers and patients alike, enhancing access to APS screening and monitoring.

In summary, the LINE Immunoassay (LIA) emerges as a valuable diagnostic tool for antiphospholipid syndrome (APS), providing heightened sensitivity, specificity, and cost-effectiveness compared to conventional methods. Its ability to detect multiple antibodies in a single assay makes it indispensable for managing APS and its associated complications.



Differentiation between APS patients (n=61, Istituto Auxologico Italiano) and asymptomatic patients with phospholipid antibodies (n=24); the LIA shows significantly higher sensitivities for APS patients compared to ELISA (EIA)\*

## Automated



## Manual



## Contact

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# Anti-Phospholipid Assays for

## DotDiver2.0

### Automated Immunoblot Analyzer

- Automated LINE & Dot immunoblot benchtop analyzer with small footprint
- User-friendly software
- Simultaneous performance of up to 24 different tests
- Ready-to-use reagents and test strips
- Automated barcode identification of test strips and cartridges
- Integrated drying of processed test strips
- Evaluation of processed test strips
- Export of results in digital file format or as print out
- Bidirectional LIS connectivity
- Low-maintenance, no liquid handling

## Anti-Phospholipid 10 Dot

Classic version with manual processing and visual for automated evaluation through scan software (i.e. Blot GAlaxy).

## Order Information



**Anti-Phospholipid IgG**

**REF 50401**

(24 x 9 Determinations)



**Anti-Phospholipid IgM**

**REF 50411**

(24 x 9 Determinations)



**Anti-Phospholipid 10 Dot**

**REF 5012**

(20 x 10 Determinations)