



## Cardiolipin and $\beta$ 2-Glycoprotein I antibodies IgG/IgM Important clinical markers for antiphospholipid syndrome (APS)

### Testing is essential for diagnosis of APS<sup>1</sup>

- APS classification criteria recommend testing for anti-cardiolipin (aCL) together with anti- $\beta$ 2-Glycoprotein I (anti- $\beta$ 2-GPI) assays<sup>1</sup>
  - In 3% to 10% of APS patients, anti- $\beta$ 2-GPI may be the only positive test<sup>1</sup>

### Combining EliA<sup>®</sup> Cardiolipin and $\beta$ 2-Glycoprotein I assays produces excellent clinical performance and supports clinical utility

- High specificity decreases the risk of overdiagnosis and inappropriate treatment

### EliA Clinical Performance<sup>2</sup>

| Assays  | Sensitivity  | Specificity  |
|---|--------------|--------------|
| Cardiolipin IgG   | 45.2%        | 81.9%        |
| Cardiolipin IgM   | 35.5%        | 86.7%        |
| Cardiolipin IgG + IgM   | 68.2%        | 75.9%        |
| $\beta$ 2-Glycoprotein I IgG  | 64.5%        | 98.8%        |
| $\beta$ 2-Glycoprotein I IgM  | 53.7%        | 92.8%        |
| $\beta$ 2-Glycoprotein I IgG + IgM                                      | 83.9%        | 91.6%        |
| <b>Cardiolipin IgG/IgM + <math>\beta</math>2-Glycoprotein I IgG/IgM</b> | <b>85.7%</b> | <b>90.4%</b> |

Table depicts the sensitivity and specificity of the single aCL EliA (>40 GPL/MPL cutoff),  $\beta$ 2-Glycoprotein I (>10 U/mL cutoff), and of their different combinations. Study design included 185 patients (62 APS and 123 controls) and compared EliA from Phadia to Orgentec and Inova ELISA methods.<sup>2</sup>

### Key study results

- EliA performed at least as well as two of the most commonly used commercial ELISA assays
- The EliA system has the first and only fully automated cardiolipin and  $\beta$ 2-GPI assays available

*“...[A] full automation of aPL [antiphospholipid antibody] tests can contribute to improve the results of these assays.”<sup>2</sup>*

— Villalta D, et al.

# EliA®: The quality results and automation you need today

## Phadia Laboratory System: Your platform for accuracy, efficiency, success

- EliA assays run on the proven Phadia 100 and 250 automated laboratory systems

## Automation ensures accuracy

- Fully automated autoimmune testing
- Accurate, standardized, and reproducible results
- One calibration curve per isotype stored for 28 days
- CLIA moderately complex

## High efficiency reduces labor costs and hands-on time

- Simple handling
  - Onboard sample dilutions
  - Continuous random access on Phadia 250
- High efficiency
  - 6-point standard calibration curve valid for 1 month
  - Discrete single-well testing
  - Flexible and efficient throughput: up to 350 results per shift
  - LIS connectivity
  - Autoimmunity and allergy on one instrument

## Phadia 100



Throughput: up to 144 tests per shift

## Phadia 250



Throughput: up to 350 tests per shift

## For advanced autoimmune diagnostics, look no further than Phadia

### References

1. Miyakis S, et al. International consensus statement on an update of the classification criteria for definite antiphospholipid syndrome (APS). *J Thromb Haemost.* 2006;4:295-306. 2. Villalta D, et al. Accuracy of the first fully automated method for anti-cardiolipin and anti- $\beta_2$ -glycoprotein I antibody detection for the diagnosis of antiphospholipid syndrome. *Ann NY Acad Sci.* 2009;1173:21-27.

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