

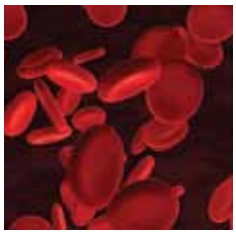


EliA®
Autoimmune assays
Excellence in Autoimmunity

Cardiolipin and ß2-Glycoprotein I antibodies IgG/IgM
Important clinical markers for antiphospholipid syndrome (APS)

Testing is essential for diagnosis of APS[1]

- APS classification criteria recommend testing for anti-cardiolipin (aCL) together with anti-ß2-Glycoprotein I (anti-ß2-GPI) assays[1]
  - In 3% to 10% of APS patients, anti-ß2-GPI may be the only positive test[1]

Combining EliA® Cardiolipin and ß2-Glycoprotein I assays produces excellent clinical performance and supports clinical utility

- High specificity decreases the risk of overdiagnosis and inappropriate treatment

EliA Clinical Performance[2]

Assays	Sensitivity	Specificity
Cardiolipin IgG	45.2%	81.9%
Cardiolipin IgM	35.5%	86.7%
Cardiolipin IgG + IgM	68.2%	75.9%
ß2-Glycoprotein I IgG	64.5%	98.8%
ß2-Glycoprotein I IgM	53.7%	92.8%
ß2-Glycoprotein I IgG + IgM	83.9%	91.6%
Cardiolipin IgG/IgM + ß2-Glycoprotein I IgG/IgM	**85.7%**	**90.4%**

Table depicts the sensitivity and specificity of the single aCL EliA (>40 GPL/MPL cutoff), ß2-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.[2]

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 ß2-GPI assays available

"…[A] full automation of aPL [antiphospholipid antibody] tests can contribute to improve the results of these assays."[2]

— 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-ß2-glycoprotein I antibody detection for the diagnosis of antiphospholipid syndrome. *Ann NY Acad Sci*. 2009;1173:21-27.

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Phadia
Setting the Standard

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