

NEW

Anti-Cardiolipin and Anti- β 2 Glycoprotein-1 S Range EIA

The **BINDAZYME™** S range anti-cardiolipin and anti- β 2GP-1 (IgG & IgM) assays are calibrated against the Sapporo monoclonal standards, (expressed in $\mu\text{g}/\text{mL}$). These monoclonal standards were introduced in recognition of the need for reproducible standardisation in the routine clinical detection of antiphospholipid antibodies.



- Anti-cardiolipin and anti- β 2GP-1 IgG and IgM assays calibrated against monoclonal standards across the whole calibration curve
- Allow reporting in quantitative units ($\mu\text{g}/\text{mL}$)
- Human β 2GP-1 provides a highly specific co-factor
- Standard BINDAZYME test format makes assays easy to automate
- Validated protocols for DSX™ and DS2™ automated systems



BINDAZYME™ Anti-Cardiolipin & Anti-β2GP-1 S Range EIA

EIA for Antiphospholipid Antibody Detection

EIA tests are recommended for the detection of anti-cardiolipin and anti-β2GP-1 antibodies to support laboratory diagnosis of antiphospholipid syndrome (APS)¹. As a result there are a variety of commercial and in-house EIA in use. However a lack of concordance in the performance and reporting between the different EIA assays for these antibodies has been noted^{2,3}.

Sapporo Standards

The Standardization Committee of the European Forum for Antiphospholipid Antibodies have supported the introduction of HCAL and EY2C9 IgG and IgM standards. These standards are monoclonal antibodies that have dual specificity for both cardiolipin and β2GP-1 (results expressed in µg/mL). The monoclonal nature of these standard preparations ensures reproducibility^{3,4,5}.

Specific BINDAZYME S Range

The S EIA IgG and IgM assays offer all the benefits of other assays in the BINDAZYME range.

All S range anti-cardiolipin and anti-β2GP-1 assays have specifically optimised common wash buffers and sample diluents. This means S range EIA components are interchangeable, facilitating their use on automated systems. Human β2GP-1 cofactor in the anti-cardiolipin S range assays gives optimal assay specificity⁶.

Optimal Testing

To obtain full benefits of the optimised S range EIA kits, the single specificity and screen anti-cardiolipin and anti-β2GP-1 EIA kits are intended to be used together and must not be mixed with other BINDAZYME anti-cardiolipin and anti-β2GP-1 EIA kits.


Monoclonal Assay Calibration Versus Simple Conversion Factor

Calibration of the S range against monoclonal standards ensures that the benefits of consistent and reproducible results are seen across the whole calibration curve. A conversion factor representative of a small part of the curve will not be accurate across the measuring range of the assay.

Binding Site recognises the need for reproducible standardisation in the clinical detection of anti-phospholipid antibodies.

The S range, calibrated to Sapporo monoclonal standards is part of our commitment to ensure greater reproducibility of results when measuring serum antiphospholipid antibodies.

Ordering Information

	WELLS	CODE
Anti-Cardiolipin IgG S EIA	96 test	MK127
Anti-Cardiolipin IgA S EIA	96 test	MK128
Anti-Cardiolipin IgM S EIA	96 test	MK129
Anti-Cardiolipin Screen S EIA	96 test	MK130
Anti-β2GP-1 IgG S EIA	96 test	MK140
Anti-β2GP-1 IgA S EIA	96 test	MK141
Anti-β2GP-1 IgM S EIA	96 test	MK142
Anti-β2GP-1 Screen S EIA	96 test	MK143

References:

- Miyakis S *et al.* International Consensus statement on an update of the classification criteria for definite antiphospholipid syndrome (APS). *J Thromb Haem* 2006;4:295-306
- Pengo, V. *et al.* Antiphospholipid antibody ELISAs: Survey on the performance of clinical laboratories assessed by using lyophilized affinity-purified IgG with anticardiolipin and anti-β2-Glycoprotein 1 activity. *Throm Res* 2007; 120: 127-133
- Fontain, M. *et al.* Persistent Problems with Standardization of Immunoassays for Anti-Cardiolipin Antibodies *Thromb Haemost* 2001; 86: 1123-1124
- Tincani, A. *et al.* Anticardiolipin Antibody Assay: a Methodological Analysis for a better Consensus in Routine Determinations. A Cooperative Project of the European Antiphospholipid Forum. *Thromb Haemost* 2001; 86: 575-583
- Ichikawa, K. *et al.* A chimeric antibody with the human γ1 constant region as a putative standard for assays to detect IgG β2-glycoprotein 1-dependent anticardiolipin and anti-β2-glycoprotein 1 antibodies. *Arthritis Rheum* 1999; 42:2461-2470.
- Cervera, R. *et al.* V Meeting of the European Forum on Antiphospholipid Antibodies *Autoimmunity Rev* 2006;5:499-507

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