

AUTOZYME™ ACL

Anti-cardiolipin IgM antibodies

- **Accuracy - calibration to Harris standards & internal controls**
- **Flexibility - kit can be run manually or on an automated system**
- **Methodology - allows simultaneous measurement**
- **Practicality - “break a well” strips allows economic use**
- **Ready to use - colour coded reagents**
- **Specificity - use of high purity cardiolipin antigen + cofactors**

• Indication

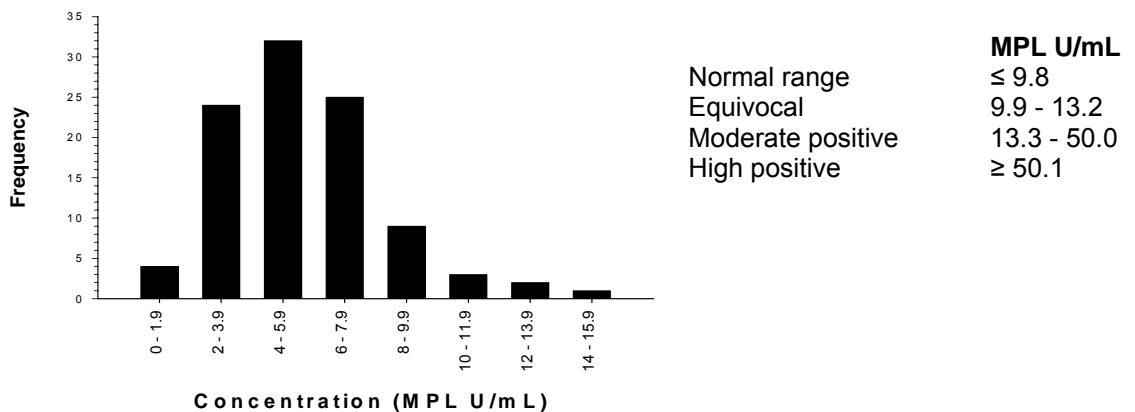
AUTOZYME™ ACL Anti-cardiolipin IgM antibodies is a sandwich immunoassay for the quantitative detection of anti-cardiolipin IgM antibodies in human serum.

• Summary and explanation of test

Anti-cardiolipin antibodies are a heterogeneous group of antibodies directed towards negatively charged phospholipids. Of the various tests available for the detection of anti-phospholipid antibodies, the anti-cardiolipin antibody test has been recognised as the method of choice.

The presence of anti-cardiolipin antibodies identifies patients at risk of venous and arterial thrombosis particularly in recurrent unexplained thrombocytopenia, recurrent foetal loss, myocardial infarction and recurrent stroke. The term anti-phospholipid syndrome (APS) refers to a combination of thrombosis, recurrent foetal loss and thrombocytopenia, together with the presence of raised anti-cardiolipin levels. Significantly raised IgA and IgM anti-cardiolipin antibodies are associated with the thrombotic events (although not to the same extent as IgG). All three isotypes should be individually assessed when evaluating patients in whom APS is suspected. Low levels of these antibodies are generally transient and not associated with APS. In summary, anti-cardiolipin antibodies can be used in the diagnosis, risk assessment and monitoring of patients with APS.

• Reference ranges



- **Related Products: AUTOZYME™ ENA, IFAB, nDNA, RF and TAB**
- **Instructions for use and Safety Data Sheets available on-line at: <http://www.clsdiagnostics.com/downloads/>**

AUTOZYME™ ACL

Anti-cardiolipin IgM antibodies

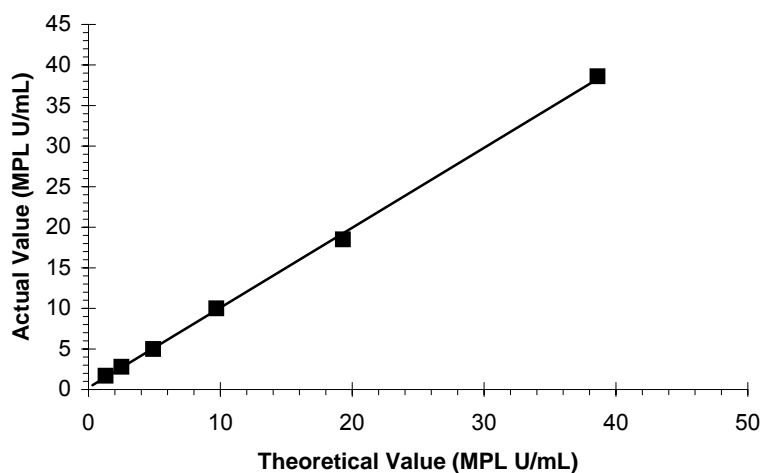
Catalogue No. Z4696



• Precision

Intra-assay precision (n = 20)		Inter-assay precision (n 3)	
Mean (MPL U/mL)	CV (%)	Mean (MPL U/mL)	CV (%)
7.3	7.8	6.6	12.3
26.2	11.3	25.6	2.2
52.8	13.1	56.9	6.4

• Linearity



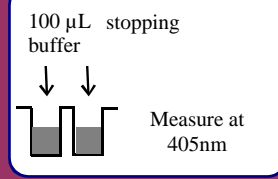
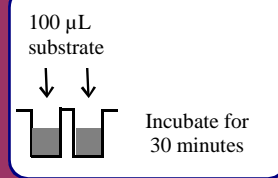
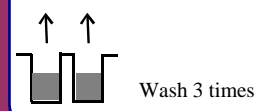
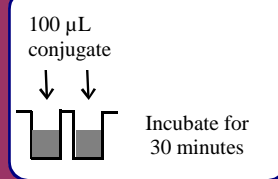
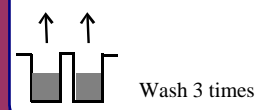
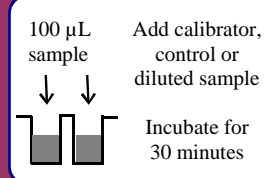
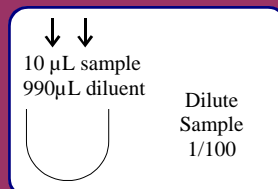
• Interfering analytes

No significant interference outside of the usual precision of the assay was detected with the following potential interferents:

Bilirubin	500 mg/L
Haemoglobin	5 g/L
Ascorbic acid	1 g/L
Lipids	10 %
hu IgG Kappa myeloma	8 mg/mL
hu IgM Lambda myeloma	60 mg/mL
hu IgA Kappa myeloma	91 mg/mL

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Test procedure



AUT ACL/IgM v03 130605