CAMBRIDGE Life Sciences

Autoimmunity Reagents: Thrombosis

AUTOZYME™ ACL

KEY POINTS:

- **Antigen: high purity cardiolipin and ß$_2$-glycoproetin 1cofactor**
- **Calibration: 6 calibrators (quantitative), to internationally recognised Reference Standards IRP 97/656 (IgG) from Dr E N Harris, Louisville, USA, and HCAL (IgG) / EY2C9 (IgM)**
- **Serum samples, Dilution: 1/100 (10µl sample+ 990µl diluent)**
- **No interference from Bilirubin, Haemoglobin, Lipids, Ascorbic Acid**
- **Assay Time: 30', 30' 30'**

INDICATION:

Quantitative detection of anti-cardiolipin IgA, IgG or IgM autoantibodies in human sera or plasma to aid the diagnosis of antiphospholipid syndrome (APS) in conjunction with other laboratory tests and clinical findings.

PRINCIPLE OF THE ASSAY:

Anti-cardiolipin antibodies are a heterogeneous group of antibodies directed towards negatively charged phospholipids. Of the various tests available for the detection of antiphospholipid 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 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.

ORDERING INFORMATION	CONFIGURATION	PART NUMBER
AUTOZYME™ ACL IgA	1 x Microplate 6 x 1.5mL Calibrators 1 x 1.5mL Negative Control 1 x 1.5mL Positive Control 1 x 100mL Sample Diluent 1 x 67mL Wash Buffer Conc (X15) 1 x 15mL Conjugate 1 x 15mL ABTS Substrate 1 x 15mL Stop Solution	Z4496
AUTOZYME™ ACL IgG		Z4596
AUTOZYME™ ACL IgM		Z4696

CE IVD 98/79/EC
For in vitro diagnostic use and Professional Use only.

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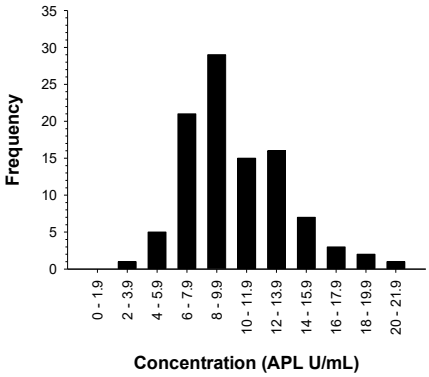
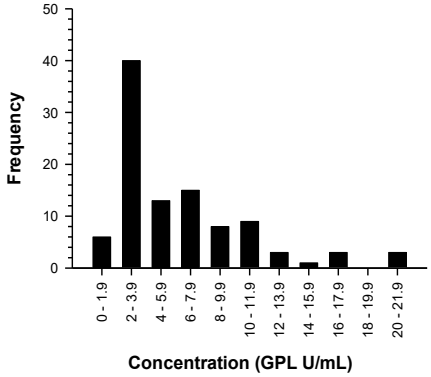
PERFORMANCE:

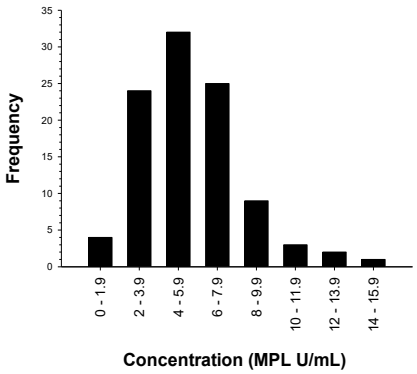
Reference Values

AUTOZYME™ ACL was used to determine the ACL IgA, IgM and IgG levels of 204 serum samples from normal blood donors with no apparent abnormalities. The data was evaluated and the following ranges obtained:

	Z4496 ACL IgA	Z4596 ACL IgG	Z4696 ACL IgM
Normal Range	≤ 10.2 APL U/mL	≤ 13.3 GPL U/mL	≤ 9.8 MPL U/mL
Weak Positive	10.3 - 14.3 APL U/mL	13.4 - 19.9 GPL U/mL	9.9 - 13.2 MPL U/mL
Moderate Positive	14.4 - 80.0 APL U/mL	20.0 - 80.0 GPL U/mL	13.3 - 50.0 MPL U/mL
Strong Positive	≥ 80.1 APL U/mL	≥ 80.1 GPL U/mL	≥ 50.1 MPL U/mL







Precision

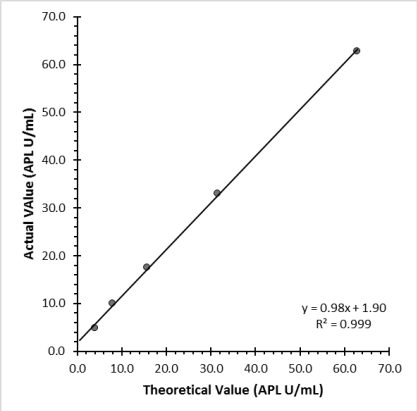
Intra-assay (n=20)	APL U/mL	CV %	GPL U/mL	CV %	MPL U/mL	CV %
Sample 1	14.1	3.5	25.9	9.0	7.3	7.8
Sample 2	38.9	5.3	63.9	7.3	26.2	11.3
Sample 3	69.9	10.1	71.2	8.5	52.8	13.1
Inter-assay (n=3)	**APL U/mL**	**CV %**	**GPL U/mL**	**CV %**	**MPL U/mL**	**CV %**
Sample 1	12.6	10.7	22.9	13.3	6.6	12.3
Sample 2	36.8	5.8	60.7	4.6	25.6	2.2
Sample 3	69.3	6.0	73.3	5.7	56.9	6.4

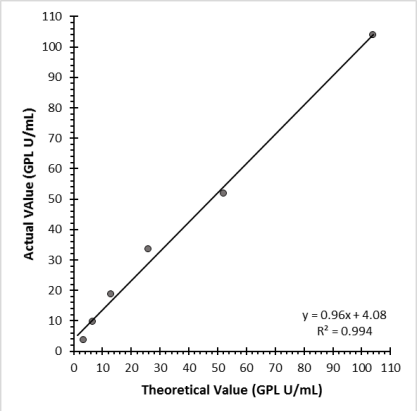
Interference

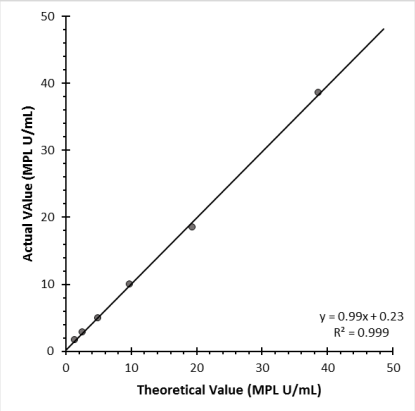
Interferent	Concentration
Ascorbic Acid	1.0 g/L
Bilirubin	500mg/L
Haemoglobin	5.0g/L
Intralipids	10% (w/v)
Hu IgG Kappa myeloma	8 mg/mL
Hu IgM Lambda myeloma	60 mg/mL
Hu IgA Kappa myeloma	91 mg/mL

No significant interference observed.

Linearity







Measuring Range

Z4496 ACL IgA: 3.0 - 100.0 APL U/mL
Z4596 ACL IgM: 0.3 - 100.0 GPL U/mL
Z4696 ACL IgG: 0.6 - 60.0 MPL U/mL
The minimum detectable concentration is defined as the concentration equal to 2 standard deviations from the mean of 20 replicate determinations of the sample diluent,.