

# AUTOZYME™ ACL Screen

## Anti-cardiolipin IgA, IgG and IgM antibodies

- *Accuracy - calibration to Harris Standards and 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*

The AUTOZYME™ Anti-cardiolipin (ACL) Screen is a sandwich immunoassay for the qualitative detection of the combined IgA, IgG and IgM class anti-cardiolipin autoantibodies in human serum or plasma. AUTOZYME™ ACL Screen results are expressed in U/mL. AUTOZYME™ ACL Screen is intended as an aid in the diagnosis of an increased risk of thrombosis in patients with Systemic Lupus Erythematosus (SLE) or lupus like disorders and the assay is suitable for use on open automated immunoassay systems.

### • *Summary and explanation of test*

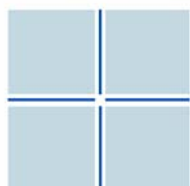
The anti-phospholipid syndrome (APS) or Hughes' syndrome is an autoimmune disease with variable and diverse clinical manifestations characterised by arterial and/or venous thrombosis, recurrent foetal loss and elevated titres of anti-phospholipid antibodies. The syndrome may be either primary or may occur in the setting of an associated disease (secondary) most frequently SLE or other autoimmune diseases. Lupus anticoagulants and anti-cardiolipin antibodies to IgG and/or IgM classes at medium to high titres are laboratory indicators of the condition as recommended by the Sapporo Criteria. Patients with secondary APS associated with SLE have more episodes of arthritis and livedo reticularis, and more frequently exhibited thrombocytopenia. ACL is seen in approximately 88% of patients. Furthermore, ACL antibodies have been found in some non-thrombotic neurological disorders like cerebrovascular insufficiency, cerebral ischemia or chorea and in myocardial infarction. Recent studies indicate that elevated levels of ACL IgA associated with respect to different ethnic groups as well as ACL IgG and IgM are found frequently in these patient groups. The determination of IgM antibodies is a valuable indicator in the diagnosis of the beginning of autoimmune diseases and there is a significant association between ACL IgM and haemolytic anaemia. A serum cofactor is needed for the detection of ACL which is identified as a 50kD protein known as  $\beta$ 2-glycoprotein 1 and this acts to facilitate the binding of ACL to cardiolipin antigen.

### • *Analytical characteristics*

Measurement of over 700 positive and negative sera samples on AUTOZYME™ ACL Screen and on AUTOZYME™ ACL IgA, IgG and IgM kits gave the following results:

|                                  |               |
|----------------------------------|---------------|
| <b>Sensitivity</b>               | <b>100.0%</b> |
| <b>Negative predictive value</b> | <b>100.0%</b> |
| <b>Accuracy</b>                  | <b>100.0%</b> |

- *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/>*



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# AUTOZYME™ ACL

## Anti-cardiolipin IgA, IgG and IgM antibodies

### Catalogue No. Z4796



#### • Accuracy

| NEQAS samples | NEQAS Classification | AUTOZYME™ ACL Screen Results | AUTOZYME™ ACL IgA, IgG, IgM Results |
|---------------|----------------------|------------------------------|-------------------------------------|
| 411           | IgG Positive         | Positive                     | IgG Positive                        |
| 441           | IgG Positive         | Positive                     | IgG Positive                        |
| 511           | IgG Positive         | Positive                     | IgG Positive                        |
| 521           | IgG Positive         | Positive                     | IgG Positive                        |
| 541           | IgG Positive         | Positive                     | IgG Positive                        |
| 542           | IgG Positive         | Positive                     | IgG Positive                        |
| 651           | IgG Positive         | Positive                     | IgG Positive                        |
| 632           | IgM Positive         | Positive                     | IgM Positive                        |
| 641           | IgM Positive         | Positive                     | IgM Positive                        |
| 442           | IgM Positive         | Positive                     | IgM Positive                        |
| 451           | IgM Positive         | Positive                     | IgM Positive                        |
| 461           | IgM Positive         | Positive                     | IgM Positive                        |
| 462           | IgM Positive         | Positive                     | IgM Positive                        |
| 531           | IgG Positive         | Equivocal                    | IgG Positive                        |
| 452           | Negative             | Negative                     | Negative                            |
| 512           | Negative             | Negative                     | Negative                            |
| 611           | Negative             | Negative                     | Negative                            |
| 622           | Negative             | Negative                     | Negative                            |

#### • Performance characteristics

- 1 – Cross-reactivity:** No cross-reactivity with Rheumatoid Factor or dsDNA antibodies that may be present in patients with SLE was observed. Neither was there cross-reactivity from myeloma sera samples.
- 2 – Interfering analytes:** There is no interference from bilirubin at 0.5mg/mL, ascorbate at 2mg/mL, haemoglobin at 5mg/mL, lipids at 10% w/v or from the use of common blood collection tube anticoagulants.
- 3 – In-use stability:** one month from first use.
- 4 – Precision:**

| Intra-assay precision (n=20) |       |        | Inter-assay precision (n=5) |       |        |
|------------------------------|-------|--------|-----------------------------|-------|--------|
| Mean (U/mL)                  | SD    | CV (%) | Mean (U/mL)                 | SD    | CV (%) |
| 1.68                         | 0.046 | 2.7    | 2.98                        | 0.074 | 2.5    |
| 1.00                         | 0.035 | 3.5    | 1.72                        | 0.063 | 3.7    |
| 0.39                         | 0.017 | 4.4    | 0.45                        | 0.011 | 2.4    |

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#### Test procedure

