

**REAADS
IgG Anti-Beta 2 Glycoprotein 1
Test Kit**

Product #: 037-001
(96 well kit)

**REAADS
IgM Anti-Beta 2 Glycoprotein 1
Test Kit**

Product #: 038-001
(96 well kit)

**REAADS
IgA Anti-Beta 2 Glycoprotein 1
Test Kit**

Product #: 039-001
(96 well kit)

- **For the specific determination of IgG, IgM, or IgA anti-B2GP1 antibodies**
- **Excellent clinical correlation**
- **Color coded reagents**
- **Total incubation time: 40 minutes**
- **Convenient, cost effective ELISA procedure**
- **Choice of single or multi-point calibration**

Background

Anti-phospholipid antibodies are a heterogeneous group of antibodies that bind to several anionic phospholipids. Most autoimmune anti-phospholipid antibodies require serum cofactors for optimal binding.

Beta 2 Glycoprotein I (B2GPI) is a protein cofactor with natural anticoagulant properties and has an affinity for negatively-charged phospholipids. Antibodies directed against B2GPI have been shown to be associated with thrombosis in individuals with systemic lupus erythematosus (SLE) and lupus-like disorders (antiphospholipid syndrome).

The presence of both anti-phospholipid and anti-B2GP1 antibodies shows a better correlation with the clinical manifestations of antiphospholipid syndrome than either of these antibodies occurring separately.

Principle

The REAADS IgG, IgM and IgA anti-B2GP1 Test Kits are indirect enzyme linked immunosorbent assays for the semi-quantitative determination of anti-B2GP1 antibodies in human serum. A single point or multi point calibrator is used to measure IgG, IgM, or IgA anti-B2GP1 antibody concentrations in G, M or A units.

Procedure

Diluted patient serum is incubated in wells coated with purified human B2GP1. Anti-B2GP1 antibodies, if present, will bind to the antigen coated wells. Following a wash to remove any unbound serum or plasma, antibodies specific to human IgG, IgM or IgA labeled with horseradish peroxidase (HRP) are added to the wells. After washing to remove unbound conjugate, a chromogenic substrate is added, resulting in a soluble colored product that is measured in a spectrophotometer at 450nm following the addition of a stop solution. Relative patient anti-B2GP1 levels are determined by comparing the absorbance of patient wells to those of the calibrator. The results of the REAADS anti-B2GP1 test are expressed in G, M or A units. Total incubation is 40 minutes at room temperature.

Clinical Performance

Clinical Specificity: serum samples from multiple healthy blood donor populations were assayed for the presence of IgG, IgM, and IgA anti-B2GPI antibodies. Specificity was shown to be 100%, 93%, and 96%, respectively for the three isotypes.

Clinical Sensitivity: an unselected SLE population was tested to determine the

clinical sensitivity of the anti-B2GPI assays. Sensitivity was 23% for IgG, 20% for IgM and 25% for IgA. The clinical sensitivity of the assay for thrombosis was determined by comparing anti-B2GPI test results from two groups of selected SLE patients: Group 1, with a clinical history of thrombosis and/or thrombocytopenia; and Group 2, with no history of thrombosis (control). The results are shown below:

Group 1: SLE + Thrombosis and/or thrombocytopenia			
	IgG	IgM	IgA
Average Value	69 G units	24 M units	106 A units
% positive	58%	42%	67%

Group 2: SLE control			
	IgG	IgM	IgA
Average Value	9 G units	9 M units	22 A units
% positive	20%	11%	11%



Corgenix, Inc.
11575 Main Street
Suite 400
Broomfield, Colorado 80020
Toll Free: 800-729-5661
Telephone: 303-457-4345
Fax: 303-457-4519
E-mail: techsupport@corgenix.com
www.corgenixonline.com