

**User's Manual**

beta2-Glycoprotein I Screen ELISA Kit

REF DEIABL321 Σ 96T**RUO**

This product is for research use only and is not intended for diagnostic use.

For illustrative purposes only. To perform the assay the instructions for use provided with the kit have to be used.

Creative Diagnostics

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PRODUCT INFORMATION

Intended Use

Beta 2-Glycoprotein 1 Screen ELISA is a solid phase enzyme immunoassay employing native β 2-glycoprotein I highly purified from human plasma for the combined quantitative and qualitative detection of IgA, IgG and IgM antibodies against β 2-glycoprotein I in human serum. Anti- β 2-glycoprotein I antibodies recognize specific epitopes on human β 2-glycoprotein I which are expressed only when β 2-glycoprotein I interacts with lipid membranes or when absorbed to other surfaces (e.g. microtiter plate). The assay is an aid in the diagnosis and risk of primary and secondary antiphospholipid syndrome (APS).

General Description

Beta 2-Glycoprotein 1 Screen ELISA is a solid phase enzyme immunoassay employing native β 2-glycoprotein I highly purified from human plasma for the combined quantitative detection of IgA, IgG and IgM anti-bodies against β 2-glycoprotein I in human serum. Anti- β 2-glycoprotein I antibodies recognize specific epitopes on human β 2-glycoprotein I which are expressed only when β 2-glycoprotein I interacts with lipid membranes or when absorbed to other surfaces (e.g. microtiter plate). The assay is an aid in the diagnosis and risk of primary and secondary antiphospholipid syndrome (APS). Antibodies against β 2-glycoprotein I belong to the group of anti-phospholipid antibodies mainly targeted against complexes composed of negatively charged phospholipids (cardiolipin e.g) and plasma proteins like β 2-glycoprotein I, prothrombin, protein C or protein S. Reactivity against isolated β 2-glycoprotein I is found, too. Thus β 2-glycoprotein I is discussed to be an autoantigen on its own. β 2-glycoprotein I, also called apolipoprotein H, is a 50 kDa β 2-globuline which is associated in vivo with lipoprotein, platelets and phospholipids and which seems to inhibit the intrinsic coagulation pathway, the prothrombinase activity and the ADP-dependent platelet aggregation. Anti-phospholipid antibodies are frequently found in sera of patients with systemic lupus erythematosus and related diseases and are typical for the secondary development of an antiphospholipid syndrome (APS). Whilst, anti-phospholipid antibodies in patients with no other autoimmune diseases characterize a primary APS. Many studies have shown a correlation between these autoantibodies and an enhanced incidence of thrombosis, thrombocytopenia and habitual abortions (as a consequence of placental infarction). The exact mechanism how pathogenic anti-phospholipid antibodies induce thrombosis has not been revealed yet.

Storage

2-8°C

Precision

Intra-assay		
Sample No.	Mean (U/ml)	CV (%)
1	2.7	0.3
2	23.7	2.7
3	46.0	3.0

Inter-assay		
Sample No.	Mean (U/ml)	CV (%)
1	2.3	0.9
2	27.3	3.9
3	54.3	5.7

Detection Range

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0 - 300 U/mL, cut-off 20 U/mL

Sensitivity

1.0 U/ml.