Method and kit for in vitro diagnosis of anti-phospholipid syndrome

KEYWORDS

- ANTIPHOSPHOLI - PID ANTIBODIES
- CARBAMYLATION
- CRYPTIC EPITOPES
- NEO - EPITOPES
- LABORATORY DIAGNOSIS

AREA

- CHEMISTRY & BIOTECHNOLOGY

CONTACTS

- PHONE NUMBERS
+39.06.49910888
+39.06.49910855
- EMAIL
u_brevetti@uniroma1.it

Priority Number
n. 102021000002306_03.02.2021.

Patent Type
Patent for invention.

Ownership
Sapienza Università di Roma 100%.

Inventors
Sorice Maurizio, Misasi Roberta, Garofalo Tina, Longo Agostina, Capozzi Antonella, Manganelli Valeria, Recalchi Serena, Ritano Gloria.

Industrial & Commercial Reference
Manufacturers of Diagnostic Kits; Use extended to all sectors dealing with Specialized Diagnostics.

Time to Market
The results of using the prototype of the invention were positive, especially for patients who are negative to conventional tests; Proposed TRL: level 5.

Availability
Cession, Research, Development, Experimentation and Collaboration.

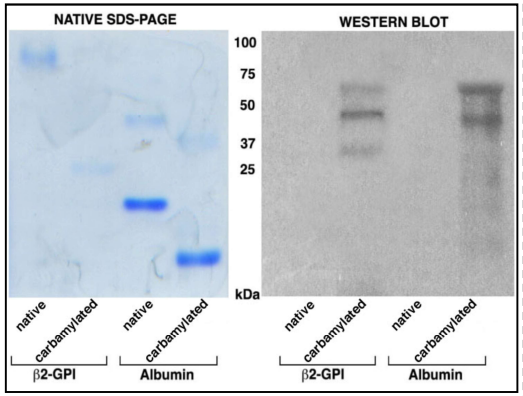


Fig. 1 Analysis of carbamylated β2GPI by SDS-PAGE and Western blot.

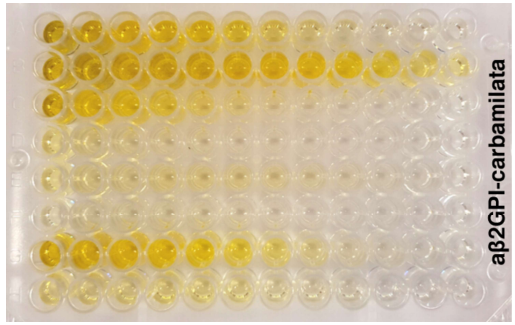
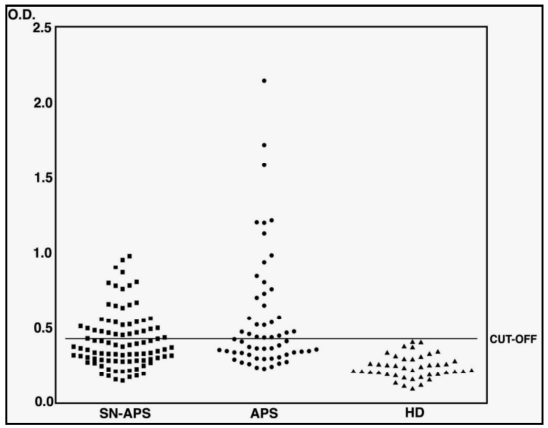


Fig. 2 Example of ELISA plate.

Fig. 3 Optical density (O.D.) of anti-carbamylated β2GPI in patients with APS and healthy donors.



Abstract

Antiphospholipid antibodies are a group of autoantibodies which, in association with thrombosis (arterial and/or venous) and recurrent abortions, characterize the Antiphospholipid Antibody Syndrome (APS). Anti-β2-Glycoprotein I (β2GPI) antibodies are the main autoantibodies used for the diagnosis of APS. There are patients with clinical manifestations of APS, but negative by laboratory diagnostic criteria.

It is essential to identify new antigenic targets for the diagnosis of APS. We demonstrate that carbamylated β2GPI is a new autoantigen of the Syndrome by proposing an in vitro analytical method, object of the invention, to detect specific antibodies to carbamylated β2GPI.

Method and kit for in vitro diagnosis of anti-phospholipid syndrome

Technical Description

The present invention includes the β2GPI protein carbamylation and the method of the invention refers to the dosage of the anti-β2GPI carbamylated antibodies by one of the frequently used immunoenzymatic methods (ELISA). To obtain an easy-to-use test, the Kit includes the carbamylated β2GPI immobilized on a solid support (96-well polystyrene plate or preferably 8 strips of 12 wells each). Alternatively, this test may be developed by chemiluminescence. The kits also contain any additional components that allow the assay to be performed, such as, for example, buffers, capture reagents, development reagents, markers, reaction surfaces, control samples, and instructions for use.

Technologies & Advantages

The laboratory diagnostic criteria of APS are Lupus Anticoagulant, anti-cardiolipin antibodies and anti-β2 glycoprotein I antibodies (by ELISA). For the definitive diagnosis of APS, in addition to a clinical positivity, it is necessary to find a positive test to at least one of the laboratory tests listed above. It is very common to find cases of seronegative patients, who present the clinical symptoms of APS, but are persistently negative to the diagnostic criteria of the laboratory. The test proposed in the invention involves substantial improvements compared to routine diagnostic tests, because it provides the use of a completely new antigen (carbamylated β2GPI) and allows to detect the presence of new antibody specificities in a larger portion of patients as compared to the current diagnostic assays.

Thus, the kit of the invention resolves an important diagnostic problem, considering that the definitive diagnosis of APS is an essential requirement for setting up an appropriate drug therapy.

Applications

The test, object of the invention, proposes a new marker to be tested and evaluated. It is innovative as compared to those currently used in the immunological diagnostics of the Antiphospholipid Antibody Syndrome. Its application is found especially in a clinical subset of the disease (seronegative APS) where it is not possible to make a diagnosis, because patients are negative to all the routine tests. In the sectors dealing with Specialized Diagnostics, this test may provide a diagnosis of seronegative patients with thromboembolic problems related to APS, allowing clinicians to initiate specific therapy able to prevent possible pregnancy pathologies and miscarriages.

CONTACTS

- PHONE NUMBERS
+39.06.49910888
+39.06.49910855

- EMAIL
u_brevetti@uniroma1.it