A Method for *in vitro* Diagnosis of Allergy and related Device

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PATENT STATUS: granted in Italy and Europe

PRIORITY NUMBER: FI2015A000110

PUBLICATION: 20/10/2016

PUBLISHED AS: IT, WO, EP

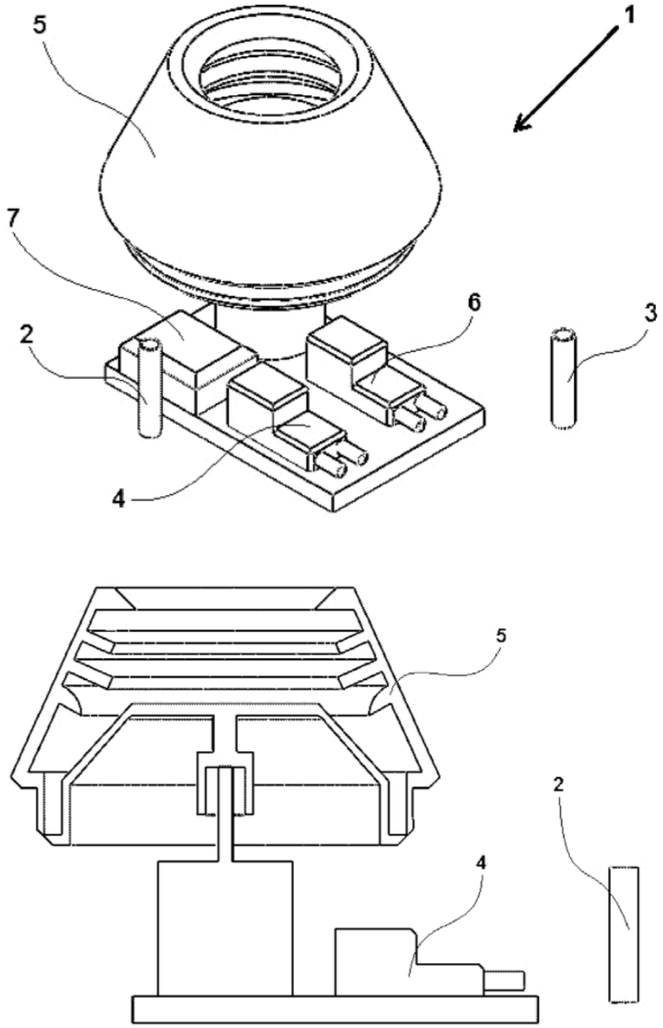
Invention

The invention consists of a method and related device for evaluating and diagnosing allergic-type reactions in a patient by analysing *in vitro* impedance changes detected by contacting the patient's serum with a given allergen.

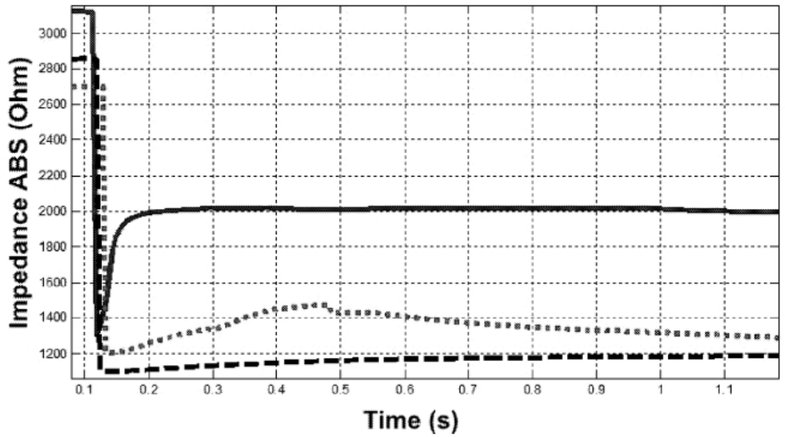
The device, connected to a data processor, first measures the impedance of the allergen alone, in terms of an object's opposition to the passage of alternating current. Subsequently, the device adds the patient's serum, containing the total immunoglobulin E (IgE) responsible for the variably severe responses to the allergen. The impedance of the allergen-serum combination is then measured, and the difference from the measurement of the allergen alone can be correlated with the concentration of total IgE in the patient's serum.

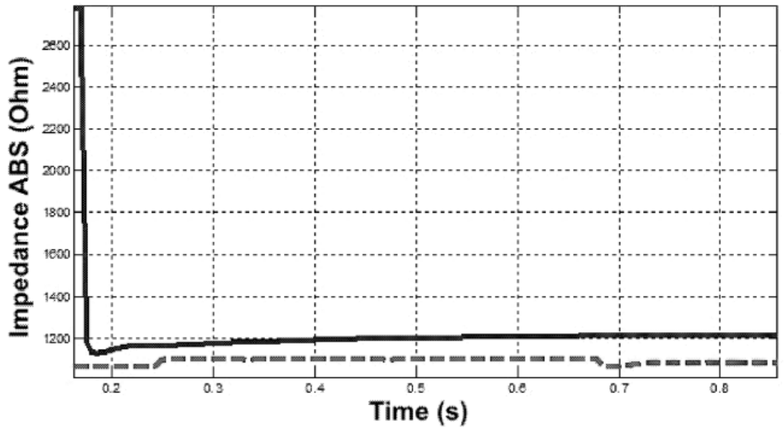
The method and device thus makes it possible not only as a diagnostic tool for a patient's sensitivity to different allergens in about five minutes and at low cost, but also to predict their severity: kinetic evaluations of the reaction between allergen and IgE may be carried out, as the greater the impedance variation, the stronger the allergic reaction, in terms of proton and electron exchanges between allergen and IgE.

Drawings & pictures



Method actuator device consisting of a container that encloses the allergen to be tested (2), a measuring unit (3), a pump (4) capable of taking a small amount of allergen from (2) to the container (5) that encloses a patient's serum sample, a second pump (6) capable of transferring the serum+allergen sample from (5) to (3) and a processor (7) capable of detecting the impedance changes detected by (3)



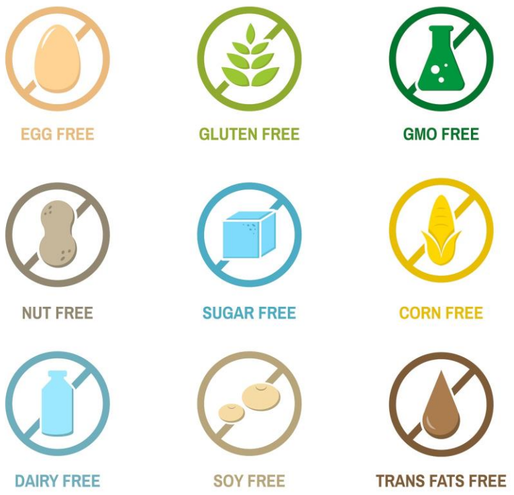


Examples illustrating the sensitivity and specificity of the system towards casein allergen
Top example: Impedance readings of sera from patients with high (__), medium (--) and low (..) levels of casein-specific IgE. Impedance readings are proportional to the amount of reactive specific IgE in the serum.
Example below: Impedance readings of sera from patients with "Vernal" keratoconjunctivitis, non-reactive towards casein; the absence of casein-specific IgE is reflected in the absence of a response from the casein system.

Industrial applications

The device implementing the method of the present invention may be of interest for health and life sciences companies for diagnostic purposes: compared to current systems, it allows for a reduction in diagnosis time (only five minutes) and a general reduction in costs, especially related to specific reagents and machinery.

Furthermore, as a kinetic evaluation tool for allergen-immunoglobulin reactions, it will further find chemical, biotechnological and nanotechnological applications for health and life sciences in general, including for biomedical research purposes.



Possible developments

The device is currently tested on several clinical serological samples to ascertain the statistical reliability of quantitative IgE assessments, and has already been approved by the ethics committee. In addition, it will be submitted for certification as a medical device.

The owners are willing to agree on joint development agreements with companies interested in the technological maturation of the device. The title is available under licence or option, exclusive or non-exclusive, in Italy and Europe.

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