CARIES RISK DIAGNOSTIC TEST

INVENTION DESCRIPTION

FISABIO has developed a test to determine the risk of caries. The diagnostic test, which we call **SIMMA** (Salivary Immune and Metabolic Marker Analysis), involves the measurement of various compounds from a drooling saliva sample collected at a specific time during the formation of plaque, which combined provide information caries risk of the individual and the source of that risk, providing the opportunity for a personalized treatment.

Our research has determined the range of values, from up to 25 compounds, in saliva samples of adult individuals with and without dental caries. Six of these compounds have shown to have a great diagnostic value. These 6 compounds may be used as "**biomarkers**" for caries disease: two of them would refer to immune competence, two to the adhesiveness of microorganisms, and two for the ability to neutralize acids or dampen pH changes.

With this information, the patent licensee may develop a measurement device of these metabolites. Alternatively, you can develop a system based on test strips similar to traditional pregnancy tests that would not require additional devices. In both cases, the test results will provide clinicians a concrete result that will tell you the **personalized treatment** for each patient, depending on the biological origin of caries risk. That is, deviations in the normal, reference values measured by the SIMMA test will indicate the dentist which hygiene product or dental treatment is appropriate for the patient, based on the biological origin of the risk of caries (immune, pH, or adhesion microorganisms), to help reverse the imbalance.

This test opens the possibility to develop three oral hygiene products adapted to the test result, which conforms to the characteristics of each patient and will counteract the natural tendency of each individual to develop dental caries, which remains the most widespread infectious disease in the world.

BUSINESS APPLICATION SECTORS

Clinical diagnosis

Oral health sector

TECHNICAL ADVANTAGES AND BENEFITS

The importance of the test is not only that it determines the risk of developing caries, but also the biological origin of the risk, that is, if there is immune imbalance, tendency to adhesion of cariogenic organisms, and / or ability to neutralize acids. This will allow a personalized preventive treatment to each individual and to prevent the risk before it appears.

Currently there are a number of diagnostic tests on the market for the caries risk, based on either genetic analysis, pH, and/or bacterial components in saliva. The SIMMA test is positioned as a more accurate test than previous ones due to the combination of different markers. It is also unique in offering a measurable outcome, indicating the percentage of a person's risk of developing caries.

Current tests based on bacterial components are quite limited, as they only measure the amount of *Streptococcus mutans* and *Lactobacillus* bacteria in saliva. These tests have little predictive value as it has been shown that there are dozens of microbial agents involved in the formation of caries in addition to these two.

Moreover, pH tests measure the ability of the saliva to regulate the acid, but it has been shown that this is only one of the factors that affect caries. With respect to genetic tests, these are still in early development phases. Furthermore, they relate the DNA mutations that predispose caries, regardless of the possible mutations that at the same time can counteract this effect.

DEVELOPMENT STATUS OF TECHNOLOGY

We have determined the exact time of sampling, how to take it and the combination of compounds to measure, providing: 1) the most reliable and accurate signal of the individual caries risk; and 2) the source of the risk, either because of an imbalance in the immune system or some anomalous physical and chemical components of saliva.

The test, which provides a reliability of 98%, was initially tested in a study that involved 40 people with and without cavities at different times of the formation of dental biofilm. Currently, the number of samples in the study cohort has been increased.

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INTELLECTUAL PROPERTY RIGHTS

European patent registered with priority date 28/NOV/2014

Trade Mark registered

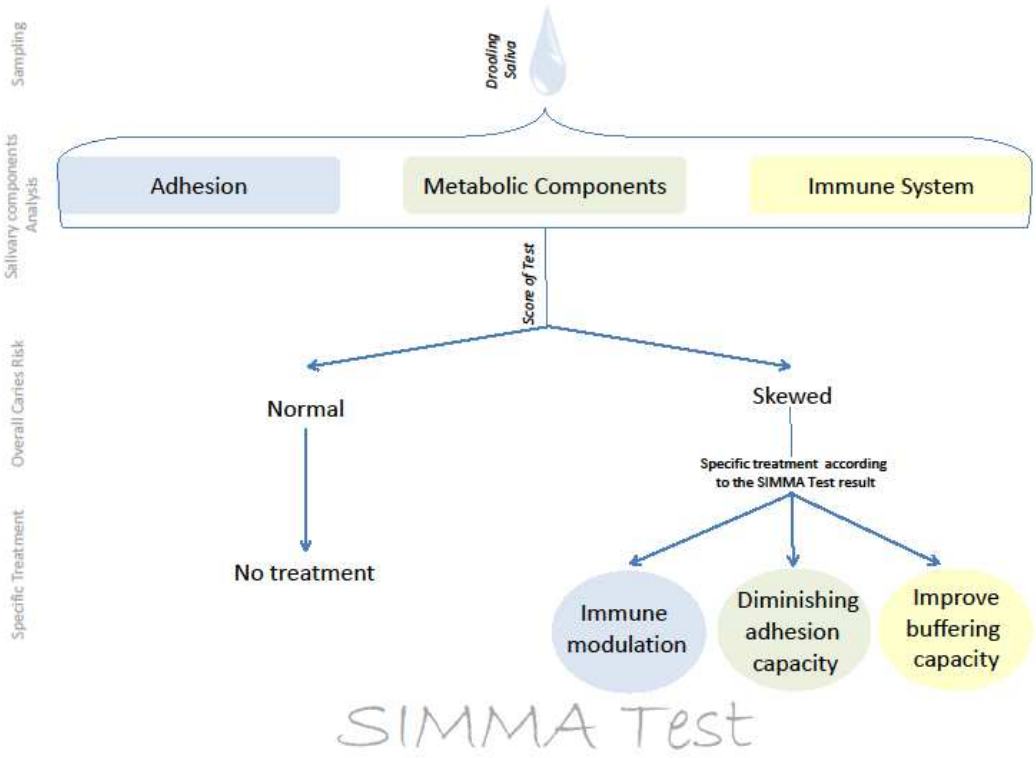
COLLABORATION SOUGHT

License Agreement with companies willing to commercialize the technology.

Co-development agreement with companies willing to transform the diagnostic test in a diagnostic kit easy to use in dental clinics.

Co-development agreement with companies in oral health willing to develop oral hygiene products tailored to test results.

RELATED IMAGES



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