

In-office or home test kit for periodontal disease based on analysis of enzyme activity in saliva

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Technology description

Problem or Unmet Need:

Periodontal disease is the most common cause of tooth loss affecting adults. It is a very common disorder, with the prevalence of severe disease being 8-12% of U.S. adults over the age of 30 years. Further, recent evidence has established periodontitis as a risk factor for several systemic conditions, including diabetes, cardiovascular disease, stroke, respiratory infections and adverse pregnancy outcomes. Dentists conventionally identify periodontitis by inspecting the tissues around the teeth with a probe and by radiographs to detect bone loss around the teeth. These methods, however, define the severity of the disease at the time of diagnosis, and in part reflect a historical record of disease and not the current progression of disease. These clinical and radiographic procedures are also time consuming. More advanced diagnostic methods involve measuring levels of biochemical markers in biological fluids. These markers are linked to inflammation associated with the development of periodontitis. Gingival crevicular fluid is produced in the gingival cuff. This fluid can be collected by placing filter strips into the crevice about each tooth. Considering the constraints associated with collecting gingival fluid from each tooth, diagnostic tests based on inflammatory markers in saliva have been proposed. Collection of saliva is simple, and analysis of the fluid offers the possibility of developing a rapid test for the patient's risk of periodontitis. The enzyme b-glucuronidase is one marker that has shown great promise as a diagnostic test for periodontitis. b-glucuronidase is a lysosomal hydrolase, and in gingival crevicular fluid and saliva is a measure of the influx of polymorphonuclear leukocytes into the gingival tissues. Analysis of this enzyme in saliva has been shown to provide an accurate measure of the severity of existing disease. Further, this marker provides information about the level of inflammation in the periodontal tissues, which is a risk factor for future disease progression.

Details of the Invention

The invention is a kit to allow in-office or at-home testing for periodontal disease in non-stimulated saliva. The test can be performed by several methods. One test utilizes substrates for b-glucuronidase that are added directly to the collected saliva. These substrates are then acted upon to result in products which are fluorescent and these levels can be compared to the standards to assess the severity of the disease. A second test utilizes substrates that, when acted upon, generate signals which are measured using colorimetric devices. A third test can measure the total b-glucuronidase levels

found in saliva by measuring labeled antibodies. All tests help diagnose the existence, past progression, and severity of periodontal disease and suggest the risk for future disease.

Application area

Testing levels of b-glucuronidase within saliva to diagnosis the severity of periodontitis

Determining total levels of b-glucuronidase in saliva with the use of antibodies

Enzymatic reaction can be measure by total fluorescent end-product created from known substrates

Useable at home or in an office setting

Advantages

Early identification of periodontal disease

Disease progression can be measured and tracked over time

Assessment of the severity of the disease is quick and robust

Activity of the marker protein can be measure with the use of colorimetric devices

Levels of protein can be measure with labeled antibodies

Generation of a fluorescent end-product from the protein's enzymatic reaction allows for easy evaluation of disease severity

Test is rapid, and can be adapted for home or office use

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