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Overview

Reported by [Bob Roehr](#) | posted January 4, 2007

Blood and urine samples are the basis for over 90% of routine medical tests performed today. But as the use of diagnostic tests proliferates, there is an increasing call for less invasive procedures in clinical practice. Oral-based diagnostics are a leading alternative, and their use has expanded rapidly over the last decade.

The search for biomarkers for disease and response to therapy has focused on blood because of its systemic reach and the robust size of the sample. But few patients take kindly to multiple blood draws, they require skilled personnel, and all those who handle samples run the risk of exposure to blood-borne pathogens.

A diagnostic that uses saliva is far less invasive and has significantly reduced risk of disease transmission. Many molecules found in blood and urine are found in saliva, though at concentrations that may be much lower than that of blood. Some tests, such as the one for detecting HIV infection, require little or no manpower or training and lend themselves to home testing. Oral-based diagnostic procedures may also be more rugged and portable, factors that are particularly important when addressing infectious disease in developing countries with a limited health care infrastructure. The mode of detection can be as sophisticated as a multi-well DNA microarray or as simple as a single antigen swab applicator/detector unit. The former is a research tool to better understand an entire sample environment, while the latter represents the ultimate manifestation of a simple, utilitarian clinical tool.

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The New York Academy of Sciences played a catalytic role in the development of the current generation of saliva-based diagnostics through a conference on the subject in 1993. It organized this second conference on Oral-Based Diagnostics, held October 10–13, 2006, at the Emerald Pointe Resort, near Atlanta, Georgia, with the goals of stimulating collaboration in development of the next generation of those tests. A forthcoming volume of the [Annals of the New York Academy of Sciences](#) will also collect the proceedings of this event.

Markers to identify and track disease

As the field of oral-based diagnostics continues to develop, researchers envision a number of potential applications, both for identifying diseases of the oral cavity and for detecting and monitoring markers of systemic disease that work their way into saliva, with blood proteins "leaking" from gums around teeth. As **Lawrence Tabak**, director of the National Institute of Dental and Craniofacial Research observed in his keynote address, "Traditionally, we have treated disease when symptoms appear and functions are lost. It is clear that we need to intervene before symptoms appear, and that will allow us to maintain normal function as long as possible."

Tabak said medicine at NIH in the 21st century is driven by the need to be predictive,

personalized, preemptive, and preventive. It is about engaging the public in taking a proactive role in their own health. Oral-based diagnostics, like the hugely successful glucose self-monitoring, could play an important role in this effort.

The first generation of current oral-based clinical diagnostics is relatively simple in that they are a qualitative measure for the presence or absence of a molecular marker for that disease or substance. However, most diseases are more complex, reflecting a range of expression of a protein crucial to a disease state, so an assay must be quantitative—measuring not merely the presence or absence of that marker but the extent to which it is present.

Often it will not be a single marker that indicates the presence of disease, but rather a constellation of them, with clinical significance lying in the balance or ratio of one, to another, to a third. Identifying disease is further complicated by the fact that even in healthy individuals, there is a range of what is considered normal. These constellations of markers may vary by age, gender, hormonal and diurnal cycle, comorbidity, and likely other factors as well.

The state of the art of OBDs

The conference featured presentations from basic researchers, clinicians, informatics specialists, device engineers, and entrepreneurs who can shape the science behind oral-based diagnostics into viable market products, and was designed to promote communication and integration of the various communities in the development to move findings in basic research into applications of clinical diagnostics. Highlights from the conference included the following:

- The number of oral fluid samples processed in central laboratories has grown to more than two million tests a year and has become one of the fastest ways of testing for substances of abuse. However, a simple, rapid, on-site equivalent of the Breathalyzer for alcohol remains an elusive goal for drugs of abuse.
- The public health sector has made widespread use of a rapid oral screening test for infection with HIV that measures antibodies and gives results in about 20 minutes. A sophisticated lab on a chip for HIV clinical care will be rolled out in 2007 for use in the developing world. It will offer rapid point-of-care diagnosis of key factors such as HIV viral load and CD4 count.
- Antibodies found in oral fluids may be produced locally in specific glands or leak from serum through crevicular junctures around the teeth. Thus, concentrations can vary depending on where the sample is collected. It reinforces the need to standardize sample collection procedures so that outcomes can be compared across trials.
- A salivary proteomics baseline of "normals" is in the process of being created, with the first iteration scheduled for completion in 2007.
- Oral cancers can be detected using a constellation of four salivary biomarkers. A handheld diagnostic that will give rapid results is in advanced development.
- Imaging technology can better delineate the extent of malignancy with oral cancer and guide surgical excision to remove all affected tissue to reduce the rate of recurrence. These findings are being validated and moved into a standard clinical setting.
- Oral sampling is opening a window on the interplay of social and environmental stresses and the body's responses to those events through the production of hormones.
- Therapeutic drug monitoring may be used to better titrate individual use of an epilepsy drug with a narrow therapeutic window.

The field of oral-based diagnostics has progressed to the point where increasing numbers of persons, from wet chemists to informatics experts, research scientists to businessmen, are excited by the opportunities and challenges of oral based markers. They see the utility of oral samples in conducting research and the longer term promise in the practice of medicine. The following pages offer a glimpse of what some of the leaders in the field are doing.

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