Salivary Test for Oral Cancer Now Available

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The burden of oral cancer

Oral squamous cell carcinoma (OSCC) is the sixth leading cancer worldwide and the fourth in African-American men. The mortality of this disease has not significantly improved in decades and this is largely due to late diagnosis. A new salivary test can help improve these statistics. This is in marked contrast to other cancers that have had significant reductions in mortality after the introduction of effective screening tests to aid in early detection.

A need for more effective screening

Published surveys document that the majority of patients do not receive oral screening examinations despite recommendations of several medical and dental organizations. Moreover this data also demonstrates that there is a lack of knowledge of both dentists and primary care physicians about oral cancer examinations.

When properly performed, oral examination alone cannot readily distinguish between malignant and benign oral lesions, making the decision for referral for consideration of oral biopsy difficult.

This is evidenced by the high rate of negative biopsies and the late stage of diagnosis of OSCC. Discriminatory biomarkers to stratify cancer risk are intended to facilitate the decision for early referral of patients at increased risk.

The science of SaliMark OSCC

SaliMark OSCC is based on more than a decade of National Institutes of Health supported research, including basic science, animal models, and clinical trials. After initial discovery studies by David Wong, DMD, DMSc, at the University of California, Los Angeles (UCLA), these markers were tested in multiple ethnic groups.

The National Cancer Institute – Early Detection Research Network (NCI – EDRN) independently validated these markers in a study of 395 subjects. Based on NCI guidelines for biomarker validation, the EDRN recommended a prospective specimen collection and retrospective blinded evaluation (PRoBE) study in the intended use population, which are patients with suspicious oral lesions considered for biopsy.

PeriRx conducted this trial in several academic medical centers in Michigan and validated a highly significant upregulation of all six prespecified messenger RNA cancer markers.

Prior studies have focused on multimarker models for risk assessment given the limited predictive power of single markers. Based on NCI guidelines, a model was developed in the PRoBE study of the intended use population using a prespecified method for model development. Housekeeping genes were incorporated into the clinical assay to ensure reproducibility and specimen integrity in daily practice.

At a sensitivity of 96%, the negative predictive value of this test was more than 98% in the prospective trial. This provides a very effective tool for identifying patients at significantly reduced risk and identifying those at increased risk.

Clinical application

This test is designed to easily fit into the flow of the dental and primary care offices. Once a suspicious patient is identified, saliva is collected using a kit with a specialized collection tube containing a molecular stabilizer.
The kit also contains the supplies necessary to send the specimen overnight by FedEx to the laboratory, and results are available online within three days on a HIPAA-secure site.

The algorithm for patient management is intended to be straightforward for the primary care dentist of medical practitioner. Low-risk patients are recommended for follow-up with the primary provider given that no test is 100% accurate.

Patients with moderate and high-risk scores are both suggested to be referred to a specialist for further evaluation. The actual quantitative test scores in the non-low-risk ranges are intended to be used by the specialist along with their clinical assessment in the decision for biopsy or further follow-up.

Salivary biomarker pipeline

SaliMark OSCC is the first of a pipeline of salivary diagnostics under development by PeriRx. A rigorous PRoBE design multicenter study is presently underway for salivary biomarkers of non-small cell lung cancer. Prior animal studies and initial clinical trials have identified discriminatory salivary messenger RNAs in lung cancer. Discriminatory biomarkers for Sjögren's syndrome have been prevalidated in prior clinical trials and are presently under further investigation to develop a robust clinical assay. Salivary biomarkers for other systemic diseases are under various stages of development.

Conclusion

SaliMark OSCC represents an opportunity to raise the bar on oral cancer, a disease that has gone unchecked for decades. This noninvasive, simple-to-use, advanced molecular technology provides a tool to help practitioners on the front lines to decide on the action plan as lesions are identified through increased patient screening.

Furthermore, salivary diagnostics for OSCC and other diseases has the ability to improve the collaboration between dental and medical practitioners as has been advocated but not as yet fully realized.

For more information, visit www.PeriRx.com.

Suggested additional reading:

1 Elashoff D, Zhou H, Reiss J, et al. Prevalidation of salivary biomarkers for oral cancer detection. *Cancer Epidemiol Biomarkers Prev*. 2012;21(4): 664-672.

2 Li Y, St John MA, Zhou X, et al. Salivary transcriptome diagnostics for oral cancer detection. *Clin Cancer Res*. 2004;10(24):8442-8450.

3 Martin JL, Gottehrer N, Zalesin H, et al. Evaluation of salivary transcriptome markers for the early detection of oral squamous cell cancer in a prospective blinded trial. *Compend Contin Educ Dent*. 2015;36(5):365-373.

4 Pepe MS, Feng Z, Janes H, Bossuyt PM, Potter JD. Pivotal evaluation of the accuracy of a biomarker used for classification or prediction: Standards for study design. *J Natl Cancer Inst*. 2008;100(2):1432-1438.

Zhang L, Xiao H, Zhou H, et al. Development of transcriptomic biomarker signature in human saliva to detect lung cancer. *Cell Mol Life Sci*. 2012;69(19):3341-3350.