



## Launching Saliva Detection Test for Oral Cancer, PeriRx Sees Opportunity for Early-Stage Disease Dx

Sep 11, 2015 | [Elizabeth Newbern](#)

NEW YORK (GenomeWeb) — PeriRx, a Pennsylvania-based developer of non-invasive oral diagnostic technology, has launched SaliMark OSCC, which it said is the first commercial saliva test for the early detection of oral squamous cell carcinoma.

The test kit contains biomarkers identified in an initial study done by [the Early Detection Research Network \(EDRN\)](#), an initiative of the National Cancer Institute. The biomarkers and the test were pre-validated by David Wong, a professor in the University of California at Los Angeles' School of Dentistry. A prospective blind study using the kit as a testing method was also performed by researchers at PeriRx the results of which were published in the May 2015 volume of [the Compendium of Continuing Education in Dentistry](#).

Throughout the testing process, scientists found that looking at these particular biomarkers was an effective way to detect OSCC. However, to increase the accuracy of detection, researchers at PeriRx decided to develop a panel that could look at multiple biomarkers at once.

According to the National Institutes of Health, oral cancer is the sixth most common cancer in the world. It is diagnosed in 45,000 Americans each year and results in 8,000 annual deaths. Early detection of the disease is key, since detection at later stages of cancer development greatly decreases a patient's chances of surviving.

The SaliMark OSCC is a multi-marker panel that looks at six oral cancer mRNA biomarkers — IL1 $\beta$ , IL8, OAZI, SAT, S100P, and DUSP1 — in DNA obtained from a patient's saliva. When a patient's saliva sample is taken, it is sent to CLIA-approved labs under legal contracts with PeriRx to perform the assays — they have exclusively in certain states — the saliva is processed to create a supernatant, treated with Life Technologies' SUPERase-IN RNase inhibitor (20 U/mL), and frozen at -80 degrees Celsius. Then RNA is isolated from the sample using Life Technologies' viral RNA isolation kit adapted on ThermoFisher's KingFisher Flex96 system. Reverse transcription and pre-amplification is performed on Life Technologies' SuperScript III RT-PCR System with Platinum Taq DNA Polymerase, and a primer set for the OSCC gene targets — obtained from the EDRN study — is prepared. Amplification was performed on the Bio-Rad CFX96 cycler and quantitative PCR is run for the prepared sample and primer set on Life Technologies' QuantStudio 12K Flex real-time PCR system.

The SaliMark OSCC test is currently being sold through three national distributors of medical supplies: Patterson Dental, Henry Schein, and Benco Dental. According to Stephen Swanick, CEO and founder of PeriRx, the firm has over 2,500 sales representatives selling its product in the field within the United States and it plans to sell the test in South America and Canada shortly.

PeriRx claims that 71 percent of the malignancies that the test detected in studies were in cancer stage 1 or 2. "[This] is a very important statistic, that our test can definitely identify and detect these patients at the earliest stages of the disease process," said Swanick. "We even [detected] some patients in dysplasia." He added that thus far the test has been well-received in the dentistry community.

Swanick told GenomeWeb that his interest in salivary diagnostics was born from a doctor-patient relationship. He was the patient, and several years back his doctor started talking to him about developments in the salivary diagnostics world. It got him interested, and he began to do research and gather together interested constituents, including PeriRx's CMO, Jack Martin. After developing their idea they decided to test it out and the long road to their new test kit began.

Funding was a big barrier to the project initially since the small, privately owned company was being funded by the founder and members of the board of directors — though the firm has since gained funding from private angel investors. "It took twice as long and three times as much money [to develop]," said Swanick. "We thought that \$5 million would enable us to get over the finish line and into the market, but we learned the hard way things don't always go the way you plan them; they take longer and cost more money to conduct clinical trials in a prospective fashion."

Testing also took a long time due to the relatively low incidence of oral cancer, which required a longer wait time to put together a large enough study group. Now that PeriRx has successfully launched its first product, it is in the process of developing other salivary diagnostic tests for the early detection of diseases including non-small cell lung cancer.

"We are actually in the middle of a similar robust prospective study trial" for the NSCLC test, Martin told GenomeWeb. He believes it will be a much shorter trial period than for the oral cancer test, since the incidence of lung cancer is, unfortunately, much higher.

Martin noted that PeriRx plans to look into possibly developing a test for Sjögren Syndrome as well, since the firm has patents on biomarkers for the disease, and it is often very difficult to diagnose the disease because of the ambiguity of its symptoms. "We've also thought it might be possible [to use salivary diagnostics] for very early detection of diabetes 1 and 2," he said.

**Testing for Life™**