



Advancing Oral Cancer Detection

An In-Depth Analysis of
BeVigilant™ OraFusion System

The Challenge

Oral cancer is a global health threat impacting more than 744,000 lives worldwide, resulting in over 365,000 deaths each year.¹ Even after decades of oral cancer research and treatment innovation, the 50% five-year survival rate has yet to improve.² Despite the large body of contributing factors, the primary driver of poor outcomes is late detection—when the disease progresses to stages III and IV. In fact, more than two-thirds of cases are diagnosed in these stages.³ This is due to inadequate detection methods with low accuracy, especially when screening for early-stage malignancies.

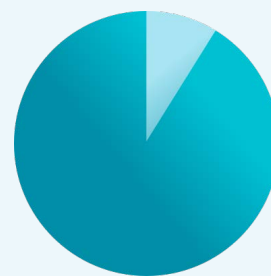
More than two-thirds of oral cancer cases are diagnosed in later stages.³

The current visual oral examination (VOE)—even when supplemented by light-based technology and oral rinses—consistently fails to differentiate between malignant and benign lesions.⁴ If an oral mucosal lesion is found, the standard practice calls for a “wait-and-watch” approach, only referring patients to specialized care when distinct malignancies are present. The decision to wait or refer to a specialist is often challenging, as current screening methods simply cannot provide enough data to make the right call. The all-too-common story of provider hesitation, fueled by the desire to make informed treatment decisions, only serves to delay time to life-saving treatment. By the time symptoms begin and the appropriate course of treatment is made clear, patients have likely entered the later stages.

At this point in disease progression, treatment must be invasive in order to increase the chances of survival. This often requires a combination of chemotherapy, radiation, and surgery. These procedures may include the removal of the lip, tongue, jaw bone, hard palate, and voice box. Because these structures are integral to daily functioning, recovery is typically a long process requiring facial or dental prostheses as well as extensive physical, occupational, and speech therapy.

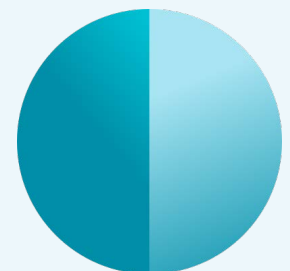
However, if oral cancer is detected and treated early, the survival rate can reach close to 90%.³ This requires an industry-wide push for improved screening and detection methods to empower more proactive care. With early-stage diagnosis and minimally invasive treatment, dental providers can redefine what a “good outcome” means for oral cancer patients—not just survival, but a high quality of life after treatment.

“Five-Year Oral Cancer Survival Rate”



90%
“Stages I and II³”

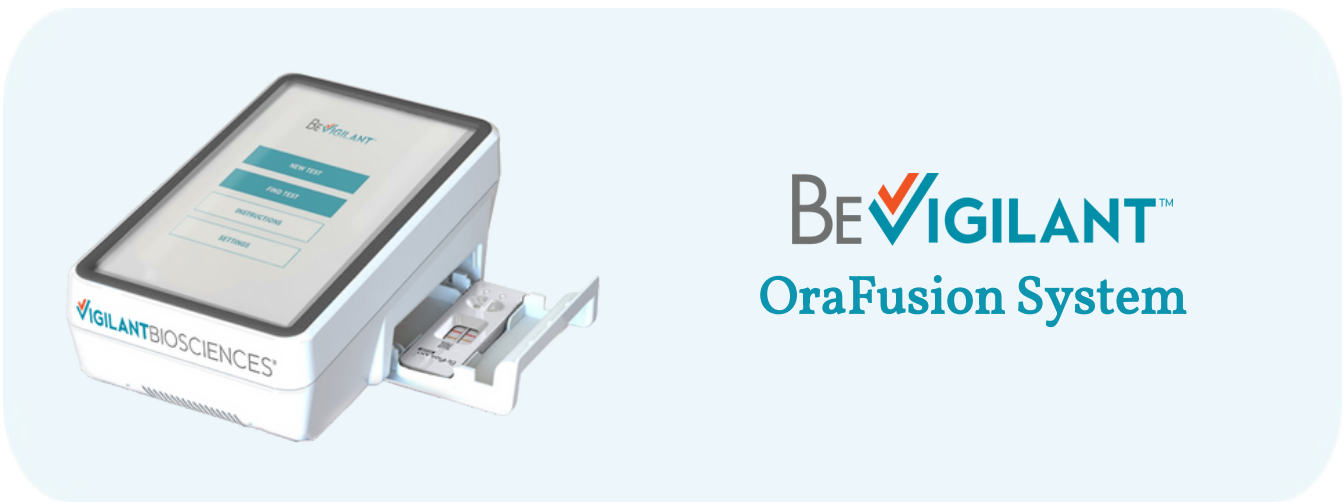
50%
“Stages III and IV²”



The Solution

The BeVigilant™ OraFusion System aims to address these challenges by providing an aid to assist dentists and clinicians in the early detection of oral cancer.

By helping dental providers identify patients with an elevated risk of oral cancer, the BeVigilant™ OraFusion System can change the trajectory of the patient journey to one characterized by earlier detection, less invasive treatment, and better outcomes.



Technology Driving the BeVigilant™ OraFusion System

The BeVigilant™ OraFusion System is a chairside oral cancer risk assessment tool that provides a semi-quantitative result in 15 minutes or less. The technology leverages early-stage biomarker identification and software-driven clinical risk factor analysis to produce a highly accurate risk assessment.

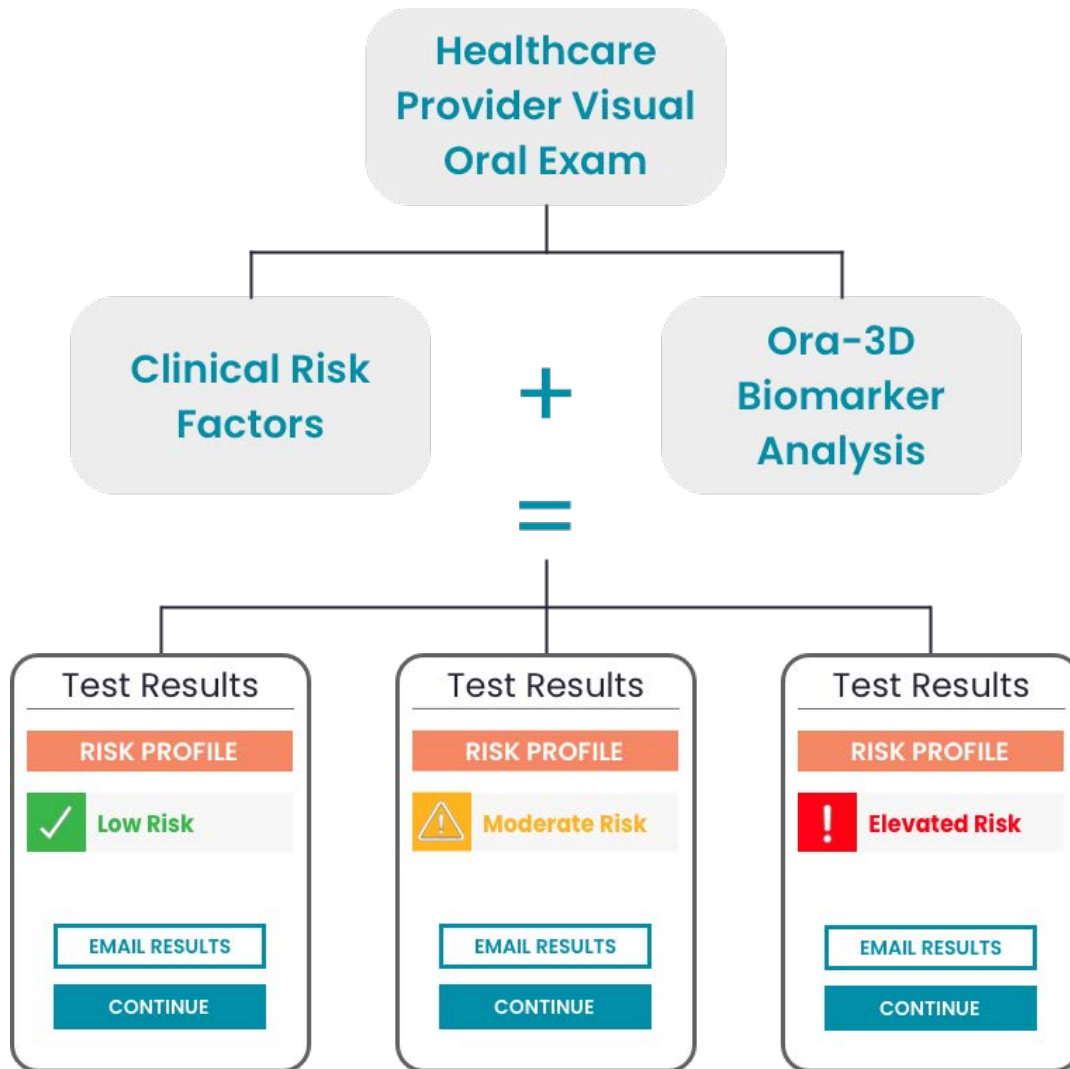
● **Early-Stage Biomarkers:**

When oral lesions become malignant, the cancerous cells overexpress certain protein-based biomarkers. After performing nearly 14,000 tests, Vigilant Biosciences® isolated two distinct biomarkers associated with early-stage oral cancer. Rather than testing for one biomarker, the BeVigilant™ OraFusion System analyzes the concentrations of both biomarkers, p16 and EGFR, to enhance testing accuracy.

● **Clinical Risk Factors:**

In order to provide the most comprehensive risk assessment, the BeVigilant™ OraFusion System performs clinical risk factor analysis for individualized results. The BeVigilant™ software utilizes artificial intelligence (AI) to determine how certain lifestyle factors impact each patient's risk of oral cancer. These factors include age, sex, race, alcohol, and tobacco use.

BeVigilant™ OraFusion Output: Biomarkers + Clinical Risk Factors



Evaluating Accuracy & Performance

Pairing dual biomarker identification with clinical risk factor analysis drives a higher level of accuracy to accelerate oral cancer detection. In a matter of minutes, the BeVigilant™ OraFusion System delivers an actionable risk assessment (low, moderate, or elevated risk) proven to minimize false positive and false negative results.⁵

- > **90-95%** Sensitivity⁵
- > **90-95%** Specificity⁵

Empowering Informed Treatment Decisions

By offering a highly accurate oral cancer risk assessment, the BeVigilant™ OraFusion System helps providers make treatment decisions with confidence. Instead of guessing which protocol is most appropriate, providers equipped with the BeVigilant™ OraFusion System can make informed decisions about whether to wait and watch or refer patients to a specialist.

The point-of-care test was uniquely designed to integrate into the standard routine of dental care. Rather than waiting days or weeks for results from a laboratory, dental providers can access results and discuss next steps during the same patient visit. With this rapidly accessible information, providers can expedite time to specialized care for official diagnosis and more effective treatment.

Where dental providers once faced uncertainty in addressing potential oral cancers, the BeVigilant™ OraFusion System brings much-needed clarity and data-driven confidence to accelerate detection for the best patient outcomes.

Sources

1. *Oral Health*. (2023, March 14). World Health Organization. <https://www.who.int/news-room/fact-sheets/detail/oral-health>
2. González-Moles, M.Á., Aguilar-Ruiz, M., & Ramos-García, P. (2022). Challenges in the Early Diagnosis of Oral Cancer, Evidence Gaps and Strategies for Improvement: A Scoping Review of Systematic Reviews. *Cancers*, 14(19), 4967.
3. *Oral and Oropharyngeal Cancer: Statistics*. (February 2023). Cancer.Net. <https://www.cancer.net/cancer-types/oral-and-oropharyngeal-cancer/statistics>
4. Kim, D.H., Kim, S.W., & Hwang, S.H. (2022). Efficacy of non-invasive diagnostic methods in the diagnosis and screening of oral cancer and precancer. *Brazilian Journal of Otorhinolaryngology* 88(6), 937-947.
5. Landis, G., Mardy, Z., Donovan, M., Nebrigic, D. (2022). *Novel Breakthrough OraFusion™ System for Suspicious Oral Lesions Risk Assessment in the Dental Practice [White Paper]*. Vigilant
6. Biosciences. Clinical Data on File.



VIGILANTBIOSCIENCES®

Changing lives together
through the transformation of
early detection of oral cancer

About Vigilant Biosciences:

Vigilant Biosciences® is leading the charge in developing cutting-edge solutions that accelerate oral cancer detection. Our point of care solution is simple, accurate*, and cost-effective. We empower clinicians working to improve patient outcomes through earlier intervention.

The innovative BeVigilant™ OraFusion System employs patented technology that detects specific protein markers clinically shown to be associated with early-stage oral cancers.



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