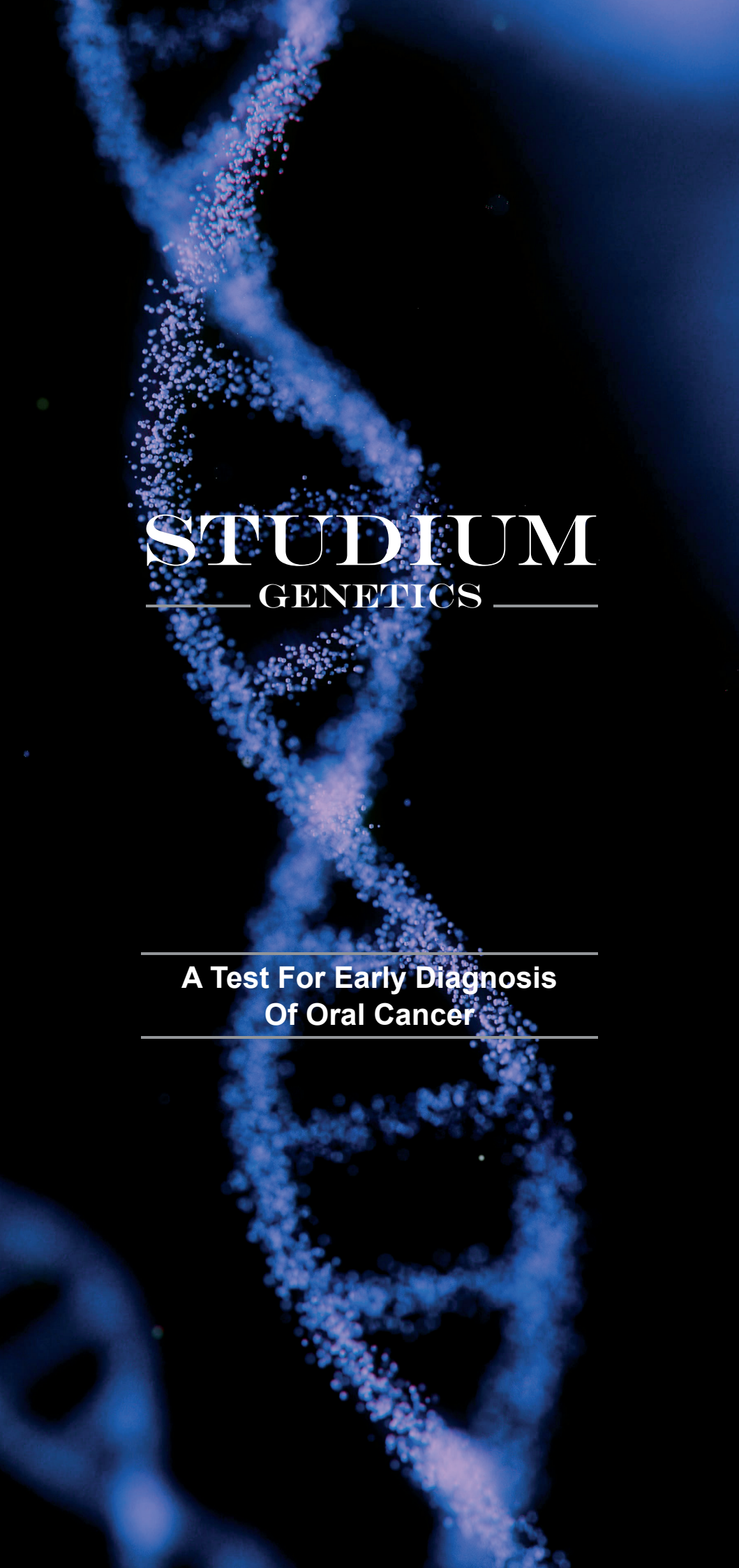
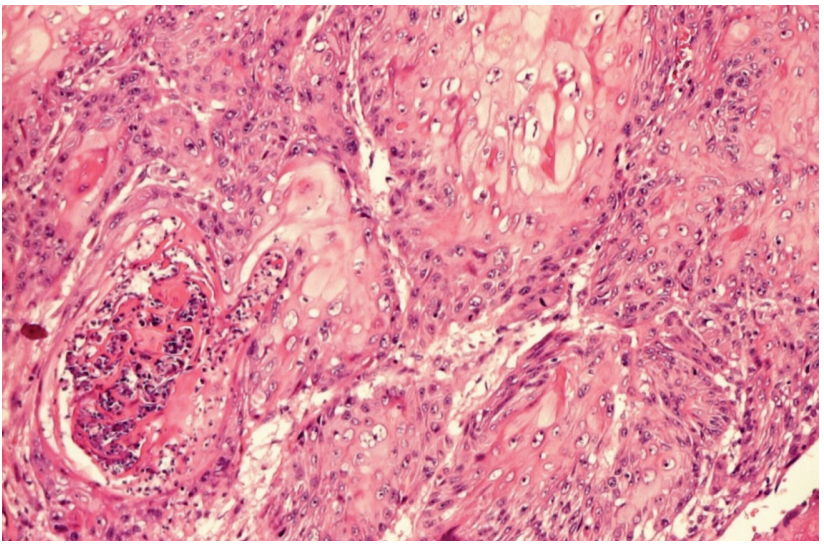

STUDIUM
GENETICS
A Test For Early Diagnosis
Of Oral Cancer

Epidemiology of Oral Cancer

Oral cavity and oropharyngeal tumours, grouped together, are the sixth most common cancer worldwide. The estimated annual incidence is approximately 750,000 cases per year, with two-thirds of these cases occurring in developing countries, and the number of oral lesions appears to be progressively increasing.
The mortality rates of these tumours have remained unchanged (50% within 5 years of diagnosis).
Risk factors are linked to smoking, alcohol consumption, and HPV infection in oropharyngeal carcinomas.



Clinical Need

Oral squamous cell carcinoma (OSCC), which accounts for 95% of all oral cavity tumours, is usually diagnosed at an advanced stage (stages III and IV), associated with a poorer prognosis.
If the disease is identified at an early stage (stages I or II), the 5-year survival rate is over 80%.
Oral cancer is typically diagnosed through an incisional biopsy, which requires an invasive surgical approach and may not be performed routinely by all healthcare professionals involved in oral care. The delay in correct diagnosis has an impact on patient survival rates, as these tumours grow rapidly.
Therefore, the development of non-invasive, easy-to-interpret methods for early identification of malignant and premalignant oral lesions is a strategy of great interest to reduce the socioeconomic impact of oral cancer.

Limitations of Current Diagnostic Procedures

Although the oral cavity is easily accessible for visual examination, several factors limit the identification and subsequent treatment of OSCC.
The current approach for screening and identifying OSCC is visual examination and palpation during an intra-oral examination by professionals in the dental, maxillofacial, or otorhinolaryngology fields during routine visits. However, this malignant lesion is not easily identifiable in its early stages and often escapes patients and professionals because it is asymptomatic and difficult to distinguish from benign lesions.
Consequently, two-thirds of cases are still diagnosed at an advanced stage (stages III-IV), when lesions infiltrate deep layers and can metastasize to neck lymph nodes.
In advanced cases, unfortunately, the survival rate decreases significantly, and surgical intervention becomes necessary, often resulting in significant loss of quality of life for the patient.

SG-OCRA™:
A Revolutionary Technology
Sensitivity: 97%
Specificity: 88%

The SG-OCRA kit contains everything needed to perform the test on 5 patients:
/ 5 brushes for collecting oral mucosa samples
/ 5 tubes for sample preservation
/ 5 bags for shipping the tubes to the accredited laboratory (prepaid shipping)

Studium Genetics has developed and patented the Oral Carcinoma Risk Algorithm (SG-OCRA™), a method for the early identification of patients with oral squamous cell carcinoma (OSCC) or its precursor, high-grade dysplasia.

The innovation is based on epigenetic analysis, specifically quantitative DNA methylation analysis using parallel sequencing (NGS). The starting material consists of cells collected from the oral mucosa using a brush, making the test absolutely non-invasive.

The markers involved in this invention are a set of 13 genes in which aberrant methylation patterns are indicative of high-grade dysplasia and/or OSCC.

Analysis of DNA methylation of these 13 genes allows for the calculation of a score using a patented algorithm to identify patients with OSCC and high-grade dysplasia.

The Studium Genetics SG-Oral Collection kit allows for sample conservation at room temperature; the preservation solution eliminates the cold chain and ensures DNA/RNA stability during sample transportation.

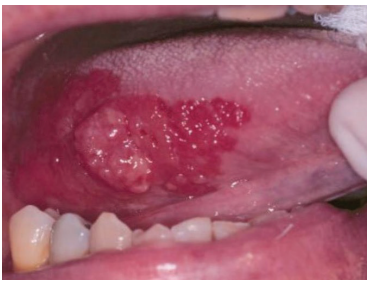
Objective of the Test for Early Diagnosis

This test is aimed at all patients with suspected oral cavity lesions.

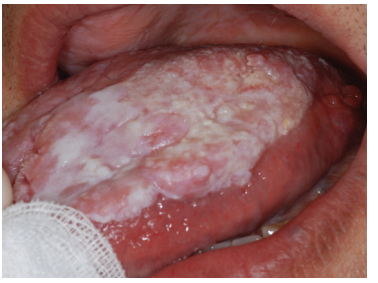
Patients at high risk of developing oral cancer are heavy smokers and alcoholics (in their 50s or 60s), although recently, there has been an increase in cases among young people without common risk factors.

A characteristic of oral cancer is that it is often preceded by potentially malignant oral lesions (OPMD) that need to be identified and monitored by dentists, maxillofacial surgeons, and otorhinolaryngologists.

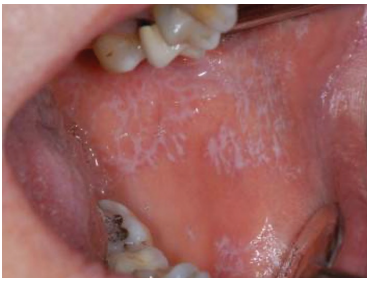
The most common forms of OPMD include leukoplakia (OL), erythroplakia, and lichen planus (OLP), as reported by the World Health Organization (WHO).



Eritroplachia



Leucoplachia



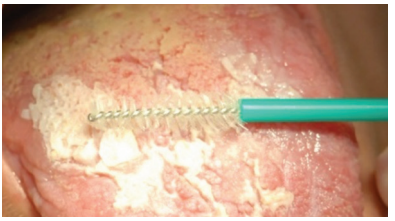
Lichen planus orale

Objective of the Test for Prognosis

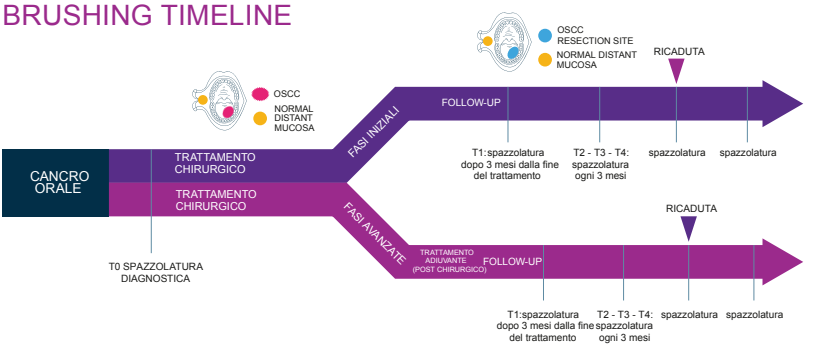
A unfavourable characteristic of oral squamous cell carcinoma (OSCC) is that, even after treatment, it presents a significant risk of developing local recurrences or second primary tumours during follow-up.
Studium Genetics' technology, in addition to its diagnostic application, also has prognostic value if the test is performed in the area adjacent to the surgical resection during follow-up visits every 3 months after surgery.
Based on data from published studies in international journals, it has been demonstrated that there are three classes of patients: those who are repeatedly negative; those who test positive at alternating phases; and those who become positive and remain so throughout the follow-up.
Compared with the first class, patients in the second class have 32x higher relative risk of developing recurrences, while for the third class, the relative risk is increased to 42x. The test has shown a diagnostic accuracy of 90% in identifying secondary neoplastic events.

Test Execution

Sample collection from oral mucosa for early diagnosis using a brush to identify OSCC/high-grade dysplasia. The same collection protocol is also performed in cases of prognostic evaluation in patients who have undergone surgical treatment for OSCC during follow-up to identify early recurrences.
Parallel sequencing of 13 genes after treatment with sodium bisulfite (NGS).
Quantitative analysis of DNA methylation and calculation of the discriminant score using a proprietary patented algorithm.



BRUSHING TIMELINE



Uniqueness of the Test

* High sensitivity without being invasive
* Based on next-generation sequencing with high-precision sodium bisulfite
* The sample can be delivered at room temperature, thanks to the preservation solution
* Provides diagnostic and prognostic information
* Identifies tumours at an early stage, improving patient survival rates and reducing the invasiveness of surgical intervention, with positive consequences for post-operative recovery and quality of life.
* Fast and inexpensive protocol, ideal for second level screening programs

Currently, there are no alternative technologies on the market for the early diagnosis of OSCC. Although various approaches have been experimented with in the past (e.g., exfoliative cytology, diagnostic optical method, etc.), none of them have been validated on clinical samples and implemented in clinical practice. The patented SG-OCRA method is available to the public, patients, and healthcare professionals. European Patent No. EP3374527

STUDIUM
GENETICS

With its headquarters in Bologna, Studium Genetics is a spin-off company of the Alma Mater Studiorum – University of Bologna that develops early diagnosis and predictive methods in the field of molecular oncology, with particular regard to oral cancer.

Studium Genetics is a company focused on precision medicine thanks to advanced genomic and epigenetic tests that have significantly improved diagnostic accuracy and prognostic prediction of cancer, neurological disorders, and complex diseases of aging.

Epigenetics provides a molecular explanation for bridging the gap between genome and environmental factors that influence the development of these diseases. Advanced research of DNA methylation alterations is Studium Genetics' main asset.

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