

# SG Oral Collection kit

Patent No.: EP3374527

## User Instruction Manual

### Cat. N. SG001-5

Number of tests: 5

Do not reuse.

Storage temperature: between 5°C and 25°C.

For in vitro diagnostic use (IVD).

DO NOT use if the product is visibly damaged.

Avoid mixing the preservation solution with sodium hypochlorite (bleach) or other strong acids or bases as it could release noxious gases.

In any case, consult the Safety Data Sheet (MSDS) and user instruction for use in different languages by contacting Studium Genetics directly or download it from the web site [www.studiumgenetics.com](http://www.studiumgenetics.com).

**Warning and precautions:** For external use only, do not drink, touch or remove the preservation solution from the collection vial. Keep out of reach of children.

The preservation solution can be harmful if ingested and may cause irritation if exposed to the skin and eyes, so avoid skin and eye contact. In case of contact with skin, wash the affected area with soap and rinse with plenty of water. If swallowed, rinse the mouth with water. Call a doctor if you feel unwell and notify your healthcare provider if irritation develops. If in eyes, rinse cautiously with plenty of water for several minutes. Remove contact lenses if present and continue rinsing.



H302: Harmful if swallowed

H315: Causes skin irritation

H319: Causes eye irritation

**Intended use:** The SG Oral Collection kit allows the collection of cells from oral mucosa in a stabilization solution ensuring the nucleic acid stability for 30 days during transport at ambient temperature. There is no need to store the specimen in a temperature-controlled room or any refrigeration. The stabilization solution also inactivates pathogens including virus, bacteria, fungi. The collection protocol can be performed by dentists, maxillofacial surgeons, otolaryngologists who can recognize suspected lesions or patients at risk to develop an oral cancer.

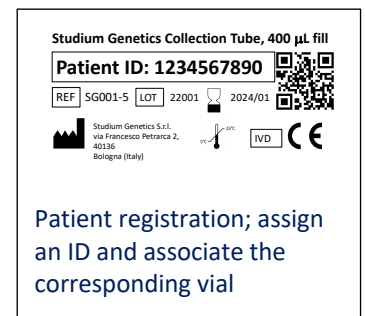
The kit includes 5 sterilized brushes with breakpoint individually packaged, 5 barcoded collection vials containing 400 µL of preservation solution, instruction for use and labels with ID for patient recording and anonymization. Samples can then be processed by a centralized NGS lab to determine the risk of having an Oral Squamous Cell Carcinoma (OSCC). The test is based on the measuring the DNA methylation of a specific set of 13 genes starting from a non-invasive oral brushing. The same method has also a prognostic value to predict recurrences: oral brushing is performed in patients treated with surgery in the regenerative mucosa covering the region that underwent the surgical OSCC excision during routine follow-up every 3 months. The test has been clinically validated and data have been published in several international peer reviewed Journals (see [www.studiumgenetics.com](http://www.studiumgenetics.com) for references).

### Content:

- 5 sterilized brushes with breakpoint individually packaged
- 5 barcoded collection vials containing 400 µL of preservation solution
- 5 labels in duplicate with ID, one for patient registry and the other to be applied on the collection vial
- Instruction for use

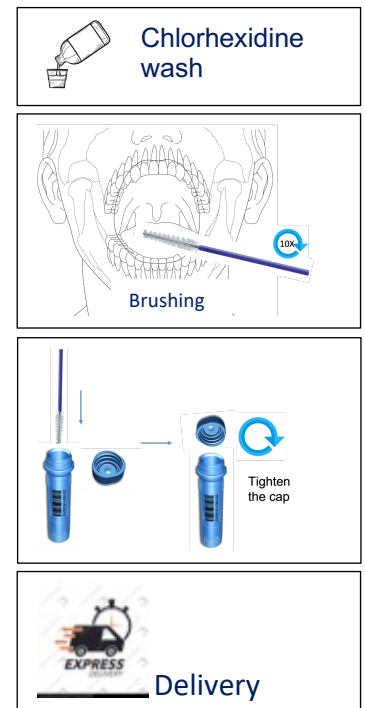
### Protocol

1. Before performing the collection protocol, ask the patient to read carefully the informed consent template (available at [www.studiumgenetics.com](http://www.studiumgenetics.com)) and fill in the blanks. It must be signed by the patient.
2. The patient must not drink alcohol or eat food shortly before the test
3. The sample must be anonymized for NGS lab using ID labels, and only the professional can associate the final score to the patient.
4. Assign a barcoded label to each patient and attach it on the record sheet (a record sheet form can be downloaded from [www.studiumgenetics.com](http://www.studiumgenetics.com)); fill in with full data of the patient and store it in a safe place. Apply the



corresponding label with the same ID on the collection vial and use it for collecting the cytobrush.

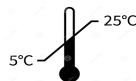
5. Perform a 0.12% Chlorhexidine Gluconate Mouthwash for 30 seconds before oral brushing sampling collection
6. Open the package containing the cytobrush
7. Exfoliated cells from oral mucosa must be collected after brushing. Gently brush with rotation and translational movements at least 10 times the area of interest with the suspected lesion. Avoid areas with necrosis, absence of epithelium and/or spontaneous bleeding. Limit the collection of whole blood and try to brush mainly keratinocytes. Use a gauze to absorb the excess of blood if present. Watch the video tutorial available at [www.studiumgenetics.com](http://www.studiumgenetics.com).
8. Holding the corresponding labeled vial upright, unscrew it.
9. Insert the collection brush, rotate it and ensure it will be completely submerged into the reagent; Apply downward pressure to break off the top of the brush at the breakpoint, leaving the lower part in the vial. The brush should be submerged into the preservation solution.
10. Attach the cap to the top of the vial and tighten the cap until completely closed. Be sure to firmly close the cap accurately.
11. The sample is now stabilized at room temperature for at least 30 days and is ready for transport.
12. Send the sample to the authorized NGS lab following the instruction of the distributor (see the authorized NGS lab list at [www.studiumgenetics.com](http://www.studiumgenetics.com)).
13. The sample will be processed and a report indicating the relative risk score correlated to the presence of an oral carcinoma will be sent within 10 working days from the date of receipt to the NGS lab.



For processing samples, the authorized NGS lab will follow the recommended protocol (SG-Oral-NGS-Protocol) for generating libraries, performing sequencing and data analysis on the Studium Genetics cloud (<https://galaxy.studiumgenetics.com>).

#### DISCLAIMER

This document and its contents are the property of Studium Genetics S.r.l. and are intended solely for the contractual use by its customer in connection with the use of the product(s) described herein and for no other purpose. This document and its contents shall not be used or distributed for any other purpose and/or otherwise communicated, disclosed, or reproduced, or referenced to in any way whatsoever without the prior written consent of Studium Genetics S.r.l. Studium Genetics S.r.l. does not convey any license under its patent, trademark, copyright, or common-law rights nor similar rights of any third parties by this document. The instructions in this document must be strictly and explicitly followed by qualified and adequately trained personnel to ensure the proper and safe use of the product(s) described herein. All of the contents of this document must be fully read and understood before using such product(s). Failure to completely read and explicitly follow all of the instructions contained herein may result in damage to the product (s), injury to persons, including to users or others, and damage to other property. Studium Genetics S.r.l. does not assume any liability arising out of the improper use of the product(s) described herein.



Studium Genetics S.r.l. via Francesco Petrarca 2, 40136 Bologna (Italy)

European and international contact information:  
Studium Genetics S.r.l., via Francesco Petrarca 2  
40136 Bologna Italy  
Customer support: +39 051 0321925  
For more information visit [www.studiumgenetics.com](http://www.studiumgenetics.com)  
Studium Genetics S.r.l. All right reserved