



## Greiner Bio-One Saliva Collection System

### Instructions for Use



#### 1. Manufacturer

Greiner Bio-One GmbH, Bad Haller Straße 32, 4550 Kremsmünster, Austria

#### 2. Intended Use

The **Greiner Bio-One Saliva Collection System**, as one complete unit (components 1 – 5), serves to collect saliva specimens for clinical-chemical analysis, and is intended for application by trained medical users.

The **Greiner Bio-One Saliva Collection System** consists of 5 components, which are applied individually.

Intended use of individual components:

- Tube 1: For cleansing mouth cavity
- Tube 2: For collection specimen
- Tube 3: Serves as collection container, and for hygienic transfer of the specimen material
- Tubes 4 and 5: Provide safe transport, storage and stabilisation of the collected specimen

#### 3. Product Description and Composition

The **Greiner Bio-One Saliva Collection System** consists of 5 components:

Item n°. 881111	Tube 1 <b>Rinsing Solution</b>	(white cap) contains 6ml Rinsing Solution (27 mM citrate buffer), colourless, medical device class 1 in accordance with MDD 93/42/EEC; microbiologically tested
Item n°. 881112	Tube 2 <b>Saliva Extraction Solution</b>	(royal blue cap) contains 4ml Saliva Extraction Solution (39 mM citrate buffer, FC&C yellow n°5 (tartrazine), yellow, medical device class 1 in accordance with MDD 93/42/EEC; microbiologically tested
Item n°. 881211	Beaker 3	(orange lid) empty, In Vitro diagnostics in accordance with IVDD 98/79/EC
Item n°. 881115	Tube 4 <b>Saliva Transfer Tube</b>	(orange cap) evacuated tube for saliva transfer contains 4mg sodium azide in crystalline form, In Vitro diagnostics in accordance with IVDD 98/79/EC <b>DO NOT OPEN!</b>
Item n°. 881116	Tube 5 <b>Saliva Transfer Tube</b>	(orange cap) evacuated tube for saliva transfer contains 4mg sodium azide in crystalline form, In Vitro diagnostics in accordance with IVDD /79/EC <b>DO NOT OPEN!</b>

#### 4. Additional Materials Required

Clock or stopwatch to time.

#### 5. Precautions and Warnings

For correct implementation of the system, the patient's active participation is required. If this is not guaranteed, or only partly possible, application is not recommended.

If the patient has a blocked nose, saliva collection using this system is not to be carried out. If there are mouth injuries (e.g. dental treatments with open wounds), saliva collection is **not** to be carried out using this system.

##### Tube 1

No precautions necessary. If mouth rinsing solution is swallowed, no health risk is involved.

##### Tube 2

The Saliva Extraction Solution contains the food dye FD&C yellow n°5 (tartrazine). If any saliva extraction solution is swallowed, there is no health risk.

Occasionally an allergic reaction to FD&C yellow n°5 (tartrazine) may occur. Persons who do not tolerate aspirin and/or benzoic acid as well as asthmatics could be affected by this. Application is not recommended, if such cases of intolerance are known.

##### Beaker 3

The round safety sticker should only be removed when saliva is being transferred into **tube 4** and **tube 5**. After transfer, the sticker should be replaced. Fingers should not be placed into the opening! Risk of needlestick! The saliva collection beaker should be kept out of children's reach.

##### Tube 4 and Tube 5

The tubes contain sodium azide, which is poisonous\*. The tubes are not to be opened (the orange cap should not be pulled off). The tubes should be kept out of children's reach. In case of accidental swallowing, doctor's advice should be sought immediately, with reference to the instructions.

\* Special precautions for people and environment:

R 28 very poisonous if swallowed. R 32 produces poisonous vapours on contact. R 50/53 very poisonous for water organisms, can cause long-term damage in waters.

## 6. Storage and Shelf-life

Storage:	Protected from light at 4°C - 25°C (applicable for all components)
Shelf-life:	See packaging label

Tubes 1 and 2 must be used immediately on opening. Opened tubes may not be saved for later use.

**Tubes 1 and 2** must be used immediately after opening. Opened tubes may not be saved for use later

## 7. Methodology

By rinsing the oral cavity with the extraction solution contained in **tube 2**, saliva and saliva extraction solution are mixed together. The saliva extraction solution contains an internal colour standard, which allows determination of the saliva quantity when using the Greiner Bio-One Saliva Quantification Kit (item n°. 881010).

## 8. General Notes on Saliva Collection

8.1	No food or liquids at least 10 minutes prior to saliva collection.
8.2	<b>The filled Tube 4 and tube 5</b> should be analysed as soon as possible. Interim storage at 2 – 8°C in a refrigerator is permissible, depending on the analytes.
8.3	<b>The 5 components of the SCS should be used in ascending numerical sequence from 1 to 5.</b>

## 9. Procedure

9.1	Open <b>tube 1</b> by pulling off the white cap and <b>rinse out</b> the oral cavity thoroughly with the contents (clear liquid). Then <b>spit out</b> . Should any contents be swallowed by mistake, there is no health risk involved (see precautions and warnings).
9.2	Open <b>tube 2</b> by pulling off the blue cap and <b>rinse</b> the oral cavity with the contents (yellow liquid) for <b>2 minutes</b> . Care should be taken that none of the liquid is swallowed, although in general, there is no risk (see precautions and warnings).
9.3	Unscrew <b>beaker 3</b> and <b>spit in</b> contents of mouth.
9.4	Screw lid back onto <b>beaker 3</b> .
9.5	<b>Remove</b> round safety sticker from <b>beaker 3</b> (see precautions and warnings).
9.6	Hold <b>beaker 3 straight or 000000000000place on a flat surface</b> , so that the end of the aspiration mouth is dipped into the liquid. Take <b>tube 4 (DO NOT OPEN – see precautions and warnings)</b> and <b>push down</b> onto the opening, overcoming a slight resistance. If this procedure has been carried out correctly, <b>tube 4</b> should fill by itself. When the <b>tube</b> is full, pull it off. NB: The tube does not fill completely. Fill volume of max. 3.5ml possible.
9.7	If liquid is left over in <b>beaker 3</b> , repeat point 9.6 with a new saliva collection tube ( <b>tube 4 or tube 5</b> ). If there is still fluid left in <b>beaker 3</b> then this is to be disposed off together with <b>beaker 3</b> (see point 9.10).
9.8	Invert <b>Saliva Collection tubes (tube 4 and tube 5)</b> several times.
9.9	Identify <b>Saliva Collection tubes (tube 4 and tube 5)</b> by writing name, surname, date of birth as well as date and time of saliva collection on the labels.
9.10	After use, seal <b>beaker 3</b> again with the round safety sticker.

## 10. Performance Characteristics, Limitations, Possible Errors

10.1	Care should be taken if <b>gums are bleeding!</b> Blood in saliva causes erroneous results.
10.2	It is absolutely necessary <b>to rinse</b> with <b>rinsing solution (tube 1)</b> ! If this step is omitted, it could have a negative effect on the system's function, in particular in regard to the transfer unit. Food leftovers or impurities from food in the collected saliva specimen can cause incorrect analysis results.
10.3	<b>For repeated saliva collections, a new saliva collection beaker should be used each time.</b> If a beaker is washed out for re-use, an average residue of 0.7ml can be expected. Due to the non-defined residue volume, repeated use of the saliva collection beaker can lead to incorrect analysis. Furthermore, an increased microbial contamination because of uncontrolled storage of the beaker between each application cannot be ruled out.
10.5	<b>Too long or incorrect storage</b> of the filled saliva transfer tube (e.g. storage for several hours in direct sunlight) can cause incorrect results.
10.5	<b>None of the Saliva Collection System components are to be used after the expiry date printed on the packaging, and they are to be disposed of correctly.</b>

## 11. Literature

Haeckel R. *Speicheldiagnostik*, Weinheim, GIT VERLAG, 1988

Haeckel R, Walker RF, Colic D: Reference ranges for mixed saliva collected from the literature. *J Chem Clin Biochem* 1989; 27:249-52

Thomas L: *Labor und Diagnose*. Frankfurt/Main: TH-Books, 6. Aufl. 2005

## 12. Date of issue

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