



Greiner Bio-One Saliva Collection System

Instructions for Use



1. System description and Intended Use

The system is intended for collection of saliva samples from both adults and young persons for clinical chemical analysis and can be used to collect saliva specimens by trained medical professionals or by self-collection.

The Greiner Bio-One Saliva Collection System consists of 3 components:

Component	Intended Use	Product description and chemical composition	Manufacturer
Tube 1: Saliva Extraction Solution	For collection of specimen	Non-sterile, royal blue cap, contains 4ml yellow Saliva Extraction Solution [citrate buffer, FD&C yellow n° 5 (tartrazine)], medical device in accordance to Regulation (EU) 2017/745, microbiologically tested	Greiner Bio-One GmbH, Bad Haller Straße 32, 4550 Kremsmünster, Austria
Beaker 2: Saliva Collection Beaker with Integrated Transfer Device	Serves as collection container and for hygienic transfer of saliva	Sterile, orange lid, empty, <i>in vitro</i> diagnostic medical device in accordance with IVDD 98/79/EC	Syntesys S.r.l., Via G. Galilei, 10/3, 35037 Teolo (PD), Italy
Tube 3: Saliva Transfer Tube	Provides safe transport, storage and stabilization of the collected specimen	Sterile, orange cap, evacuated tube for saliva transfer, contains ammonium sulfate and sodium azide in crystalline form, <i>in vitro</i> diagnostic medical device in accordance with IVDD 98/79/EC; DO NOT OPEN!	Greiner Bio-One GmbH, Bad Haller Straße 32, 4550 Kremsmünster, Austria

2. Additional Materials Required

Clock or stopwatch.

3. 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.
- Saliva collection using this system is not to be carried out when the patient has a blocked nose or if there are mouth injuries (e.g. dental treatments with open wounds).
- Do not use the product if gums are bleeding! Blood in saliva causes erroneous results.
- The Saliva Collection System is **not to be used after the expiry date** printed on the packaging and is to be disposed of correctly.
- Do not use if package is damaged.
- Incorrect storage of the collected saliva sample (for example storage during several hours in direct sunlight) can lead to incorrect results.
- In some cases, extreme discoloration of the saliva sample can affect the optical measurements, e.g. after consumption of food containing a lot of colour. Therefore, it is recommended to wait 10 minutes and then take a new saliva sample.
- Use only for laboratory analysis.
- Use gloves and PPE equipment to reduce the risk of contamination.
- Please refer to the instructions for use of the assay manufacturer for detecting the analyte of interest in saliva.
- Keep out of flame or heat sources, which might damage the products.
- Store in a dry place.

NOTE: Only applicable for member states of the European Union: Should any serious incidents occur in relation to the product, these must be reported to the manufacturer and the competent authority in the member state, in which the user/patient is established.

Tube 1

The Saliva Extraction Solution contains the food dye FD&C yellow n° 5 (tartrazine). Generally, if any saliva extraction solution is swallowed, there is no health risk and it is not required to seek medical attention. Occasionally, an allergic reaction to FD&C yellow n° 5 (tartrazine) may occur. Persons who do not tolerate aspirin and/or benzoic acid could be affected by this. Application is not recommended, if such cases of intolerance are known.

Beaker 2

- Remove the round safety sticker only when saliva is being transferred into **tube 3**.
- Do not insert fingers into the opening where the integrated transfer device is located, as there is a risk of needlestick injury.
- Keep the saliva collection beaker out of reach of children.
- After use, promptly reseal the opening of the lid of **beaker 2**, where the integrated transfer device is located, with the round safety sticker.
- The beaker must be disposed of in an appropriate disposal container in accordance with general hygiene guidelines and legal regulations. For users for **self-collection** of saliva samples: please also follow the procedures of the institution where the collection kit was obtained.

Tube 3

- **Tube 3** contains sodium azide, which is poisonous*.
- Do not open **tube 3** (the orange cap should not be pulled off).
- Keep **tube 3** out of reach of children.
- In case of accidental swallowing, seek immediate medical attention and refer to these instructions.

* Hazard Statement Codes according to CLP Classification (Regulation (EC) No 1272/2008) for the substance sodium azide:

H300 Fatal if swallowed.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

Supplementary Hazard Statement Code(s):

EUH032 Contact with acids liberates very toxic gas.

4. Storage and Shelf-life

Storage:	Store all products at 4°C - 25°C and avoid exposure to direct sunlight. Tube 1 must be used immediately after opening. Opened tubes may not be saved for later use. Beaker 2: keep dry
Shelf-life:	See packaging label




5. Methodology

By rinsing the oral cavity with the extraction solution contained in **tube 1**, saliva and saliva extraction solution are mixed. This means that the saliva sample is diluted with saliva extraction solution. When quantitative analysis should be performed with the collected sample, the saliva proportion should be determined by means of the **Greiner Bio-One Saliva Quantification Kit** (see IFU 980217). The saliva extraction solution contains an internal standard that enables the determination of the saliva quantity when using the Quantification Kit.

6. General Notes on Saliva Collection

- Do not consume food or liquids at least 10 minutes prior to saliva collection.
- For users for **self-collection** of saliva samples: **The filled tubes 3** should be taken/ transported to the doctor or to the laboratory as soon as possible. Storage at 2°C - 8°C in a refrigerator is permissible.
- All components of the Saliva Collection System (SCS) should be used in numerical sequence.














7. Procedure

7.1		Open tube 1 by pulling off the blue cap and rinse the oral cavity with the saliva extraction solution (yellow liquid) for 2 minutes . Care should be taken that none of the liquid is swallowed (see precautions and warnings).
7.2		Open the lid of beaker 2 by turning it in an anti-clockwise direction. Spit contents of mouth into beaker 2 . NOTE: To achieve the complete fill volume of 3.5 ml in tube 3, the minimum fill level in beaker 2 should be 5 ml (the volume is indicated by the marking on the scale of the beaker).
7.3		Close the lid of the beaker 2 by turning it in a clockwise direction until it is firmly closed to prevent leakage.
7.4		Remove round safety sticker from the lid of beaker 2 (see precautions and warnings) and keep it.
7.5		Place beaker 2 on a flat surface, so that the luer adapter is dipped into the liquid. Insert first tube 3 (DO NOT OPEN – see precautions and warnings) with the cap down into the opening of the lid, where the integrated transfer device is located, overcoming a slight resistance. If this procedure has been carried out correctly, tube 3 should fill by itself. When the tube is filled, pull it off. NOTE: The tube does not fill completely. Maximum fill volume of 3.5ml possible.
7.6		If liquid is left in beaker 2 , repeat step 9.5 with a further tube 3 . After use, reseal the integrated transfer device of beaker 2 with the round safety sticker. The beaker must be disposed of in an appropriate disposal container in accordance with general hygiene guidelines and legal regulations. If there is still liquid left in beaker 2 , it is to be disposed of together with beaker 2 .
7.7		Invert all filled tubes 3 several times (5x).
7.8		Identify all filled tubes 3 by writing name, surname, date of birth as well as time of saliva collection on the labels or follow the specified procedure of the institution where the kit was obtained.

8. Disposal

The components of the collection kit must be disposed of in an appropriate disposal container in accordance with general hygiene guidelines and legal regulations. For users for **self-collection of saliva samples**: please also follow the procedures of the institution where the collection kit was obtained.

9. Label information

	Manufacturer		Consult instructions for use		Keep away from sunlight
	Use-by date		Sterilized using irradiation		Keep dry
	Batch code		Do not re-use		Do not use if package is damaged
	Catalogue number		<i>In vitro</i> diagnostic medical device		
	Temperature limit		Medical device		

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