



Greiner Bio-One Saliva Collection System

Instructions for Use



1. Manufacturer

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

2. 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 for self-collection.

Intended use of individual components:

Tube 1: For collection of specimen
Beaker 2: Serves as collection container, and for hygienic transfer of the specimen material
Tubes 3: Provide safe transport, storage and stabilization of the collected specimen

3. Product Description and Composition

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

Tube 1 Saliva Extraction Solution	(royal blue cap) contains 4ml Saliva Extraction Solution [citrate buffer, FD&C yellow n° 5 (tartrazine)], yellow, medical device class 1 in accordance with MDD 93/42/EEC, microbiologically tested
Beaker 2	(orange lid) empty, In Vitro Diagnostics in accordance with IVDD 98/79/EC
Tube 3 Saliva Transfer Tube	(orange cap) 2 x evacuated tube for saliva transfer contains ammonium sulfate and sodium azide in crystalline form, In Vitro Diagnostics in accordance with IVDD 98/79/EC; DO NOT OPEN!

4. Additional Materials Required

Clock or stopwatch to time.

5. Precautions and Warnings

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).

Tube 1

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, and a doctor need not be informed.

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

The round safety sticker should only be removed when saliva is being transferred into **the tubes marked with a 3**. After transfer, the sticker should be replaced. Fingers should not be placed into the opening because there is risk of needlestick. The saliva collection beaker should be kept out of children's reach. After use, promptly seal **beaker 2** again with the round safety sticker. The beaker must be disposed of in an appropriate disposal container in accordance with the procedures of the facility.

Tubes 3

Tube 3 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 is very poisonous if swallowed. R 32 produces poisonous vapours on contact. R 50/53 is very poisonous for water organisms and can cause long-term damage in waters.

6. Storage and Shelf-life

Storage:	Protected from light at 4°C - 25°C
Shelf-life:	See packaging label

Tube 1 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 1**, saliva and saliva extraction solution are mixed together. The saliva extraction solution contains an internal standard, which is used to determine the saliva quantity in the clinical chemistry laboratory quantity when using the Greiner Bio-One Saliva Quantification Kit.

8. General Notes on Saliva Collection

8.1	No food or liquids at least 10 minutes prior to saliva collection.
8.2	The filled tubes 3 should be taken/ transported to the doctor or into the laboratory as soon as possible. Storage at 2 – 8°C in a refrigerator is permissible.
8.3	All components of the SCS should be used in numerical sequence.

9. Procedure

9.1	 <p>Open tube 1 by pulling off the blue cap and rinse the oral cavity with the contents (yellow liquid) for 2 minutes. Care should be taken that none of the liquid is swallowed, although in general, there is no risk (see precautions and warnings).</p>
9.2	 <p>Unscrew beaker 2 and spit in contents of mouth.</p>
9.3	Screw lid back onto beaker 2 . Do not close it too tightly as this could block the nozzle.
9.4	Remove round safety sticker from beaker 2 (see precautions and warnings) and keep it.
9.5	 <p>Hold beaker 2 on a flat surface, so that the end of the aspiration mouth is dipped into the liquid. Take first tube 3 (DO NOT OPEN – see precautions and warnings) and push down onto the opening, overcoming a slight resistance. Do not push down excessively as this could block the nozzle. If this procedure has been carried out correctly, tube 3 should fill by itself. When the tube is full, pull it off. <i>NOTE: The tube does not fill completely. Fill volume of max. 3.5ml possible.</i></p>
9.6	If liquid is left over in beaker 2 , repeat point 9.5 with further tubes 3 . After use, seal beaker 2 again with the round safety sticker. The beaker must be disposed of in an appropriate disposal container in accordance with the procedures of the facility. If there is still fluid left in beaker 2 then this is to be disposed of together with beaker 2 .
9.7	Invert all filled tubes (3) several (5 x) times.
9.8	Identify all filled tubes (3) by writing name, surname, date of birth as well as time of saliva collection on the labels or according to the institution's policy.

10. Performance Characteristics, Limitations, Possible Errors

10.1	Care should be taken if gums are bleeding! Blood in saliva causes erroneous results.
10.2	Incorrect storage of the collected saliva sample (for example storage during several hours in direct sunlight in a parked car) can lead to incorrect results.
10.3	The Saliva Collection System is not to be used after the expiry date printed on the packaging, and is to be disposed of correctly.
10.4	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.
10.5	Please refer to the instructions for use of the assay manufacturer for detecting the analyte of interest in saliva.

11. Label information

	Manufacturer		Temperature limit
	Use-by date		Consult instructions for use
	Batch code		Sterilized using irradiation
	Catalogue number		Do not re-use

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