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:

<table>
<thead>
<tr>
<th>Component</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tube 1 (Saliva Extraction Solution)</td>
<td>(royal blue cap) contains 4ml Saliva Extraction Solution [citrate buffer, FD&amp;C yellow n° 5 (tartrazine)], yellow, medical device in accordance to Regulation (EU) 2017/745, microbiologically tested</td>
</tr>
<tr>
<td>Beaker 2</td>
<td>(orange lid) empty, in vitro diagnostic medical device in accordance with IVDD 98/79/EC</td>
</tr>
<tr>
<td>Tube 3 (Saliva Transfer Tube)</td>
<td>(orange cap) 2x evacuated tube for saliva transfer contains ammonium sulfate and sodium azide in crystalline form, in vitro diagnostic medical device in accordance with IVDD 98/79/EC; DO NOT OPEN!</td>
</tr>
</tbody>
</table>

4. Additional Materials Required
Clock or stopwatch.

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).
- 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.
- 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.
- Please refer to the instructions for use of the assay manufacturer for detecting the analyte of interest in saliva.

NOTE: 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 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.

6. Storage and Shelf-life
<table>
<thead>
<tr>
<th>Storage:</th>
<th>Protected from light at 4°C - 25°C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shelf-life:</td>
<td>See packaging label</td>
</tr>
</tbody>
</table>

Tube 1 must be used immediately after opening. Opened tubes may not be saved for later use.
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 that enables the determination of the saliva quantity when using the Greiner Bio-One Saliva Quantification Kit.

8. General Notes on Saliva Collection

| 8.1 | Do not consume 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 to the laboratory as soon as possible. Storage at 2 – 8°C is permissible. |
| 8.3 | All components of the Saliva Collection System (SCS) should be used in numerical sequence. |

9. Procedure

9.1 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).

9.2 Unscrew the lid of beaker 2. Spit contents of mouth into beaker 2.

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 the lid of beaker 2 (see precautions and warnings) and keep it.

9.5 Place beaker 2 on a flat surface, so that the nozzle 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. 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 filled, pull it off. NOTE: The tube does not fill completely. Maximum fill volume of 3.5ml possible.

9.6 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 the procedures of the institution where the kit was obtained. If there is still liquid left in beaker 2, it is to be disposed of together with beaker 2.

9.7 Invert all filled tubes 3 several times (5x).

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 follow the specified procedure of the institution where the kit was obtained.

10. Disposal
- The collection kit must be disposed of in an appropriate disposal container in accordance with the procedures of the institution where the kit was obtained.
- The general hygiene guidelines and legal regulations for the proper disposal should be considered and followed.

11. Label information

| Manufacturer | Consult instructions for use |
| Use-by date | Sterilized using irradiation |
| Batch code | Do not re-use |
| Catalogue number | In vitro diagnostic medical device |
| Temperature limit | Medical device |

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