



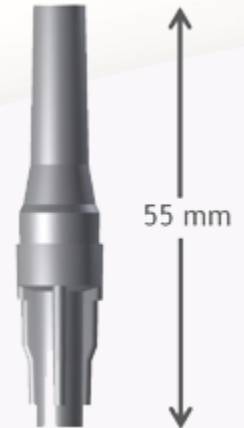
Collection Methods: Passive Drool using the Saliva Collection Aid | FDA Listed

Introduction: Whole saliva collected by passive drool is the gold standard when collecting oral fluid for biological testing. It avoids localized secretions of specific salivary glands providing a more consistent specimen. Whole saliva can be easily evaluated for volume collected and for salivary flow rate. Free from being compromised by absorbing materials used with other collection methods, whole saliva can be assayed for all analytes of interest.

The Saliva Collection Aid (SCA) is an ideal collection tool for collecting whole saliva (passive drool). Its ease of use reduces participant burden and improves compliance for collecting whole saliva.

The Saliva Collection Aid offers the following benefits:

- ✓ Simple and easy to use, single use
- ✓ Individually packaged in a clean, foil pouch (*non-sterile*), (item 5016.02)
- ✓ Ready-to-go instructions
- ✓ Comfortable, no-mess collection
- ✓ Universal fit with external threaded cryovials
- ✓ Vented design reduces sample foaming
- ✓ Collection directly into cryovials, reducing freezer storage space
- ✓ Use for participants 6 years of age and older*
- ✓ Constructed of polypropylene
- ✓ Eliminates time and material needed to transfer specimen to storage vials in the lab



Patent No.
US9498191B2

*NOTE: Sample collection with passive drool is designed for saliva donors who can follow simple instructions. For children younger than approximately 4 years of age, there may be wide ranging individual differences in their capability of collecting whole saliva. Thus, we encourage pilot study.

Passive Drool Cautions:

1. Use only as directed; Use each Saliva Collection Aid only once.
2. Do not use this device for children under the age of three (3), or without adult supervision.
3. Do not disassemble or pull apart device; discard if disassembled.

Materials Needed:

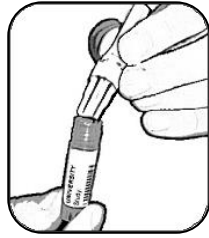
- Cryovials (Salimetrics Item No. 5004.01-06)
- Saliva Collection Aid (Item No. 5016.02 or 5016.02B)
- Bar-coded labels (Item No. 5009.07)
- 2" swab storage tubes boxes (Item No. 5023.05)

Instructions for Use:



Step 1:

If packaged, open foil pouch and remove the Saliva Collection Aid (SCA). Otherwise, proceed to Step #2.



Step 2:

Place ribbed-end of the SCA securely into a pre-labeled collection vial (see *Caution 3* above).



Step 3:

Allow saliva to pool in mouth. Then, with head tilted forward, **gently** guide saliva through the SCA into the vial. Fill to the required volume.*



Step 4:

Remove and discard SCA. Attach cap to collection vial and tighten.

*NOTE: Reserve a small amount of air space in the vial to accommodate liquid expansion during freezing.

Sample Handling and Processing (*As described in the Saliva Collection Handbook*):

- Immediately after collection, freeze samples at or below -20°C . If freezing is not possible, refrigerate immediately at 4°C and maintain at this temperature for no longer than necessary (ideally less than 2 hours) before freezing at or below -20°C (temperature of a regular household freezer).
- Samples stored for more than 4 months should be frozen at -80°C .
- Freeze-thaw cycles should be minimized for some analytes. It is critical that storage conditions are researched prior to initiation of sample collection.
- It is recommended that tubes be organized into cryostorage boxes (9x9 grids, 81 tubes) before storing or shipping.

How to Reference this SalivaBio Device in Your Research (Recommended)

"Whole saliva samples were collected with SalivaBio's 2 mL cryovials and the Saliva Collection Aid (exclusively from Salimetrics, State College, PA), a collection device specifically designed to improve volume collection and increase participant compliance, and validated for use with salivary [Analytes]."

References are available online at; <http://salimetrics.com/collection-system/passive-drool>

Developed in collaboration with the **Center for Interdisciplinary Salivary Bioscience Research** at the **Johns Hopkins University School of Nursing**