CS-5001.06 | Rev. 13, 17Apr20





Collection Method: SalivaBio Children's Swab (SCS)



FDA Listed

The SCS has been validated by Salimetrics for collecting saliva for the analysis of: Cortisol, Alpha-Amylase (sAA), Chromogranin A (CgA), Cotinine, Immunoglobulin G (IgG), Interleukin-1 Beta (IL-1β), Interleukin-6 (IL-6), Melatonin, Osteocalcin, Secretory IgA (SIgA), Testosterone, Uric Acid and DNA.

Introduction: SalivaBio Swabs are intended for the collection of saliva samples for analysis. The SalivaBio Children's Swab (SCS) (Item No. 5001.06, 50/pk) is recommended to help increase participant compliance for children from 6 months to 6 years of age. The SCS may also be used for non-human/animal saliva collection, based on the size of the species and the researcher's preference.

SalivaBio Children's Swab Cautions:

- Use only as directed.
- Collecting saliva for analytes other than those approved by Salimetrics require validation prior to use.
- This device is clean packaged, not sterile.
- To ensure safety and proper use, a copy of this instruction sheet must be distributed to each device user.
- Store out of reach of children.
- Adult assistance and supervision is **required** during use.
- Inspect device before use. **DO NOT USE** if cuts or tears are present.

Additional Materials Needed:

- Swab Storage Tube (SST), 17x100mm (Item No. 5001.05)
- Bar-coded labels (Item No. 5009.07)
- 4" swab storage tube boxes (Item No. 5023.00)
- Optional: SalivaBio 2 mL cryovials (Item No. 5004.01-06)
- Optional: 3 cc or 5 cc syringe (Item No. 5015.02)
- Optional: Scissors

Instructions for Use: Human/Animal Participants

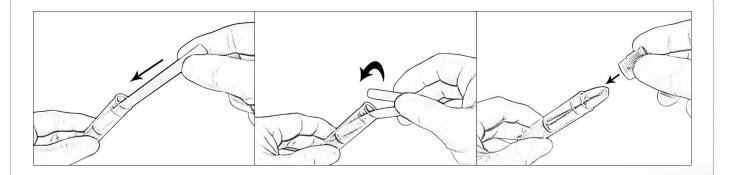


If estimating flow rate, see *Effects of Mouth Location and Flow Rate on Salivary Analytes* in the Saliva Collection Handbook (online at www.salimetrics.com).



Salivary flow rate varies by individual; collecting sufficient volume is essential to obtaining valid test results. Please refer to the Salimetrics guidelines for minimum collection volume for the analyte(s) you are testing.

- 1. Peel back protective package and remove the SCS. Do not use swab if cuts or tears are present.
- 2. Securely hold one end of the SCS device and place the other end under the subject's tongue (when possible). With small children or non-human subjects, it may only be possible to collect pooling saliva (at the corners of the mouth or under the tongue). Collect for a full 60-90 seconds by resting the swab inside the mouth, or **collect in intervals** by re-introducing the swab into the mouth as needed, until the lower third of the swab is saturated (some participants may require longer than 90 seconds of total collection time).
- 3. Immediately after collection, use one of the following procedures for storing the sample:
 - a. If storing the swab in a Swab Storage Tube for centrifugation in lab
 - 1. Remove cap and insert the *saturated* end of the swab into the swab basket of the swab storage tube (SST).
 - 2. Fold over the dry end of the swab into the swab basket.
 - 3. Recap SST tightly. *Note:* Do not throw away any parts of the tube assembly.



- b. To immediately assess volume in the field, use compression to recover the sample
 - 1. Remove plunger from a 3 cc or 5 cc syringe.
 - 2. Insert the swab into the syringe barrel, *saturated end first*.
 - 3. Cut off the protruding dry end of the swab (or double-over the dry end and insert into syringe barrel).
 - 4. Replace plunger into syringe and squeeze the swab to express saliva into a cryovial.
 - 5. Repeat collection procedure if additional volume is required.
 - 6. Cap tube tightly. You may discard swab, unless DNA analysis is required.

Note: The compression method recovers slightly less volume from the swab than centrifugation.

Label the exterior of the SST as shown with an identifying, bar-coded, cryo-label (*required for samples sent to Salimetrics SalivaLab).
 Do not use paper labels – they will fall off when frozen.



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 -20°C (temperature of a regular household freezer) or below. We recommend organizing samples in 4" storage boxes (7x7 grids, 49 tubes/box).
- You may store saliva samples at -20°C (or below) in the swab or in the Swab Storage Tube for up to 4 months.
- Extract and transfer saliva samples to screw-cap cryovials and store at -80°C for long-term storage periods >4 months.
- Freeze-thaw cycles should be minimized for some analytes. Determine storage conditions prior to sample collection.
- If processing samples in-house prior to freezing, centrifuge the storage tube for 15 minutes at 1500 g to extract the saliva. You
 may discard swab basket and swab <u>unless</u> further DNA testing is expected. Keep SST in upright position. Recap tube and
 proceed with freezing.
- All samples must be frozen at -20°C or below for a minimum of 2 hours, thawed, and centrifuged prior to laboratory testing.

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

"Saliva samples were collected using the SalivaBio Children's Swab (exclusively from Salimetrics, State College, PA), a synthetic swab specifically designed to improve volume collection and increase participant compliance, and validated for use with salivary [Analytes]."

References available online at; http://www.salimetrics.com/collection-system/childrens-swab



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