



Standard Operating Procedure

Infant Saliva Collection Method

I. POLICY: The Puerto Rico Clinical and Translational Research Consortium (PRCTRC) ensure the safety and well-being of employees, laboratory personnel, study coordinators, and those involved in the saliva collection.

II. PURPOSE: The objective of this Standard Operating Procedure (SOP) is to outline the method for the proper collection of saliva safely.

III. Area(s) of Responsibility: This SOP applies to the Principal Investigator (PI), laboratory personnel, authorized research collaborators including students and research participants.

IV. Procedures:

Salimetrix Saliva Bio swabs are made from non-toxic, inert polymer which is guaranteed for consistency across all lots, making it ideal for longitudinal and multi-participant group studies. These devices are manufactured in longer lengths and narrower widths to allow one end of the swab to be held by a parent or technician while the other end is placed in the child's mouth. The diameters are appropriate for the size of children's mouths. The polymer material is durable and can withstand chewing, and its taste and texture are also acceptable to children.

Use one the Saliva Bio Infant's Swab (SIS) (Item No. 5001.08) per collection (2 will be needed per visit).

To avoid potential choking hazard while collecting saliva samples, **never leave a child unattended.**

To avoid potential discomfort, collect saliva for a maximum of 1 minute. The volume of sample recovered from the SIS is typically in the range of 200-1000 μ L.

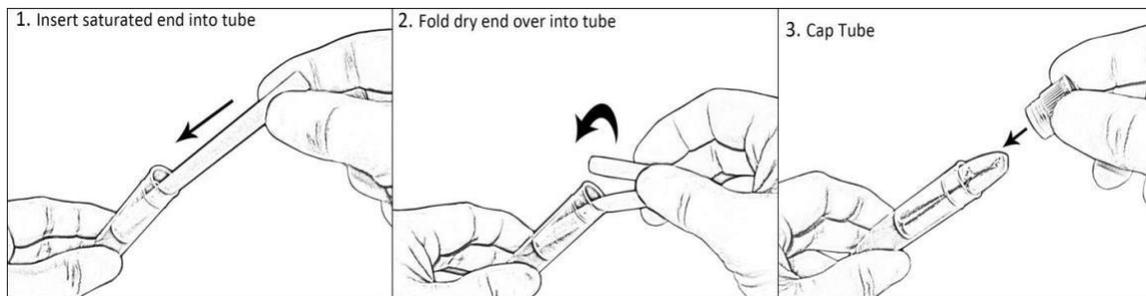
A total of approximately 1 milliliter (about 1/5 of a teaspoon) of saliva will be collected by natural flow by gently placing a tube in the corner of the infant's mouth for about 30-60 seconds. The saliva sample will be performed twice per visit: the first time before starting the EEG recording and a second time about 10 minutes later.

Instructions for Use

1. Retrieve a new SIS, peel open the outer package and remove the device.
2. Securely hold one end of the device and try to place the other end under the child's tongue. With infants it may only be possible to collect pooling saliva (often at the corners of the mouth or under the tongue). You can try to collect for the full 60 seconds at once 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 (1 minute total).

3. a) For recovery by centrifugation, place the saturated SIS into the Swab Storage Tube by inserting the saturated end first, followed by doubling over the dry end into the opening, and finally using the cap or plunger to push the entire swab into the interior space (see Diagram).

b) For recovery by immediate compression, use a 3-5 mL syringe. *Note: The compression method allows to determine if sufficient saliva has been collected on the first attempt, and the procedure can be repeated if necessary. Some researchers prefer to cut free the saturated portion of the swab before placing it in the centrifuge tube or syringe. If the swab is used to collect samples for analytes that are affected by saliva flow, however, it is advised to place the entire swab into the tube or syringe, in order to estimate saliva flow rates, as described above under Effects of Mouth Location and Flow Rate on Salivary Analytes.*



4. Label the sample with participant ID number and collection date (never with subject's name or any other personal identifier).

5. Store sample in a leak-proof bag with the biohazard symbol.

6. Place the sample into the transported box with ice until transported to the PRCTRC Lab, located in room number 122.

V. Safety Precautions:

1. Inspect device for tears or imperfections. **DO NOT USE** if cuts or tears are present.
2. Saliva is a body fluid which can be infectious. It must be handled with care.
3. Always handle used saliva collection devices with gloves to avoid exposure as well as contamination of the sample
4. Store out of reach of children. When not used as directed these devices may represent a choking hazard for children.
5. Dispose used saliva collection devices into biohazard bags. Use only as directed.