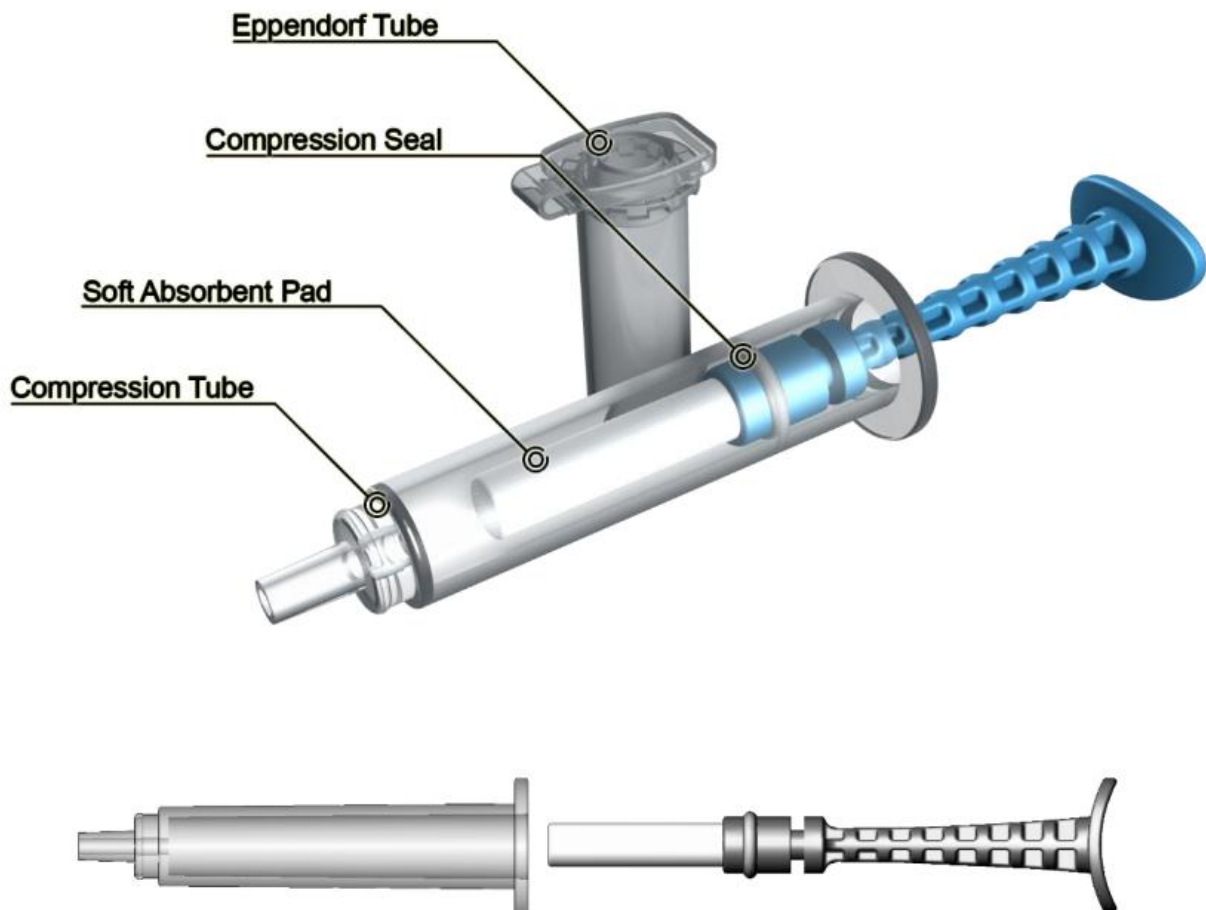


Micro-SAL™ Infant Saliva Collection Kit

Catalogue number: SALV-009

Note: For Research Use Only [RUO]. Not for Use in Diagnostic Procedures.



Intended use

- The Micro-SAL™ Infant Saliva Collection Kit is intended for the controlled, standardized collection and transportation of saliva (oral fluid) specimens from infants for subsequent testing, analysis, or research applications. The kits do not provide any diagnosis of disease.
- Ideal for the easy collection of saliva samples from infants.

Principles of the device

- The Micro-SAL™ Infant Saliva Collection Kit is a proprietary, patented system intended for the standardized collection of whole saliva (oral fluid) from infants.
- The Micro-SAL™ Kit features a cylindrical absorbent pad that facilitates rapid collection times. Saliva is released from the absorbent pad used to collect the specimen by compressing the pad through a narrow bore tube connected to a standard Eppendorf tube.

Materials provided

- Micro-SAL™ Infant Saliva Collection Device.
- Clear Plastic Compression Tube.
- 2.0 mL Eppendorf Tube.

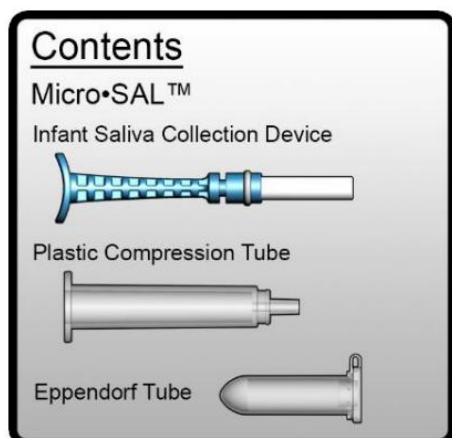
Instructions for use

- PLEASE READ THE COMPLETE INSTRUCTIONS BEFORE PROCEEDING TO COLLECT THE SAMPLE. FAILURE TO FOLLOW THESE INSTRUCTIONS CAREFULLY COULD PRODUCE SUB-OPTIMAL RESULTS.
- Prior to collection, review the detailed instructions below.
- Do not allow the infant to eat or drink for at least 10 minutes before starting the collection process.

Step by step instructions

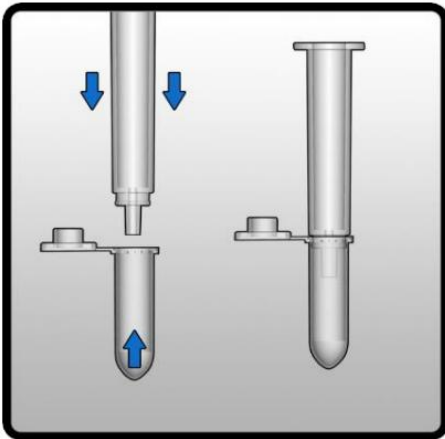
- Ensure collection is continued until the Sample Volume Adequacy Indicator visually changes, confirming sample sufficiency (Figure 4 below).

1.



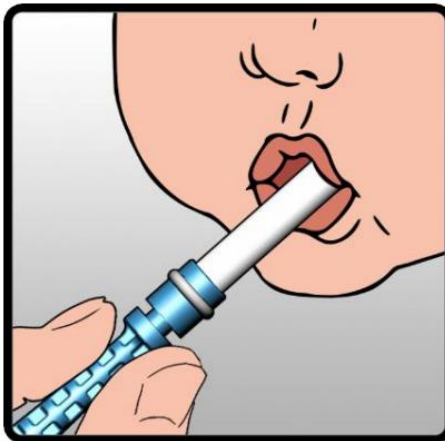
Open the package and place the contents on a clean and dry surface.

2.



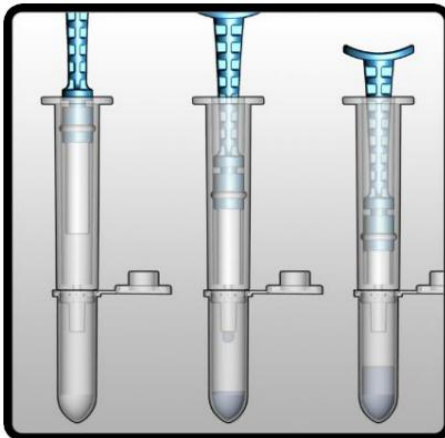
Firmly attach the Eppendorf tube provided to the base of the Plastic Compression Tube.

3.



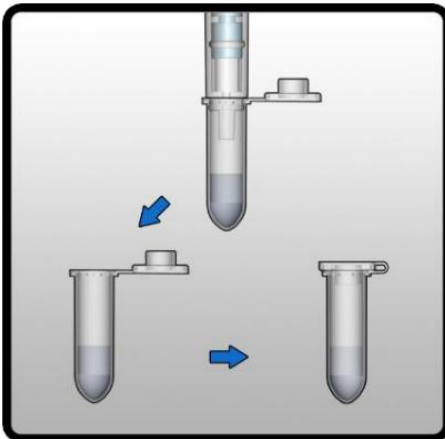
Place the tip end of the white absorbent collection pad of the Micro-SAL™ device into the mouth of the infant where saliva pools, and collect until the pad is saturated.

4.



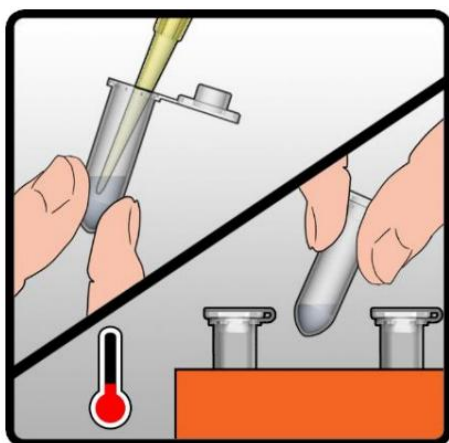
Place the white absorbent pad end into the Plastic Compression Tube holding the Micro-SAL™ device in an upright and vertical position and firmly push the plunger downwards to transfer saliva from the absorbent pad into the Eppendorf Tube. Push and hold for 15 seconds.

5.



Gently remove the Eppendorf Tube from the end of the Plastic Compression Tube. Add stabiliser/preservative (not provided), if required, and close the lid on the tube tightly.

6.



Process the collected sample immediately or store for future analysis, according to the requirements of the analyte(s) to be tested.

Precautions and notes

- DO NOT ALLOW THE INFANT TO DRINK OR EAT WHILE COLLECTION IS IN PROGRESS.
- DO NOT REUSE OR SUBSTITUTE KIT COMPONENTS.
- Kits are for single use only. Used collectors and samples should be disposed of in accordance with local requirements for clinical waste.
- Do not use kits beyond the expiration date printed on the pouch.
- Prior to use, record subject information on the Eppendorf Tube.
- During sample collection, ensure that the subject does not chew or suck on the absorbent collection pad.
- The absorbent material used to collect specimens contains no added salts, preservatives or other agents.
- Analysis of whole saliva collected using the Micro-SAL™ Infant Saliva Collection Kit should be done according to validated protocols according to assay requirements.
- Salvivo Ltd. and Oasis Diagnostics® Corporation provide no warranty as to the suitability of the Micro-SAL™ Infant Saliva Collection Kit, for any given application, other than the Intended Use described herein.
- Micro-SAL™ Infant Saliva Collection Kit are rigorously tested for compliance with United States Pharmacopeia (USP) for non-sterile products but may be provided in sterile form upon request.
- Store at room temperature (15-30°C) until the expiration date written on the exterior of the pouch.
- The Micro-SAL™ Infant Saliva Collection Kit does not diagnose any disease.

Ordering information

- Micro-SAL™ Infant Saliva Collection Kits are sold in units of 50 kits per box and 10 boxes (500 kits) per case. Please contact Salvivo Ltd. regarding your requirements.

Final note

- Manufactured by Oasis Diagnostics® Corporation in the United States.
- This device is protected by US and EU Patents including US Patent Numbers 7618591, 7927548, 8273305 and others.

Technical support

- For Technical Support please contact Salvivo Ltd. via the contact details below.



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