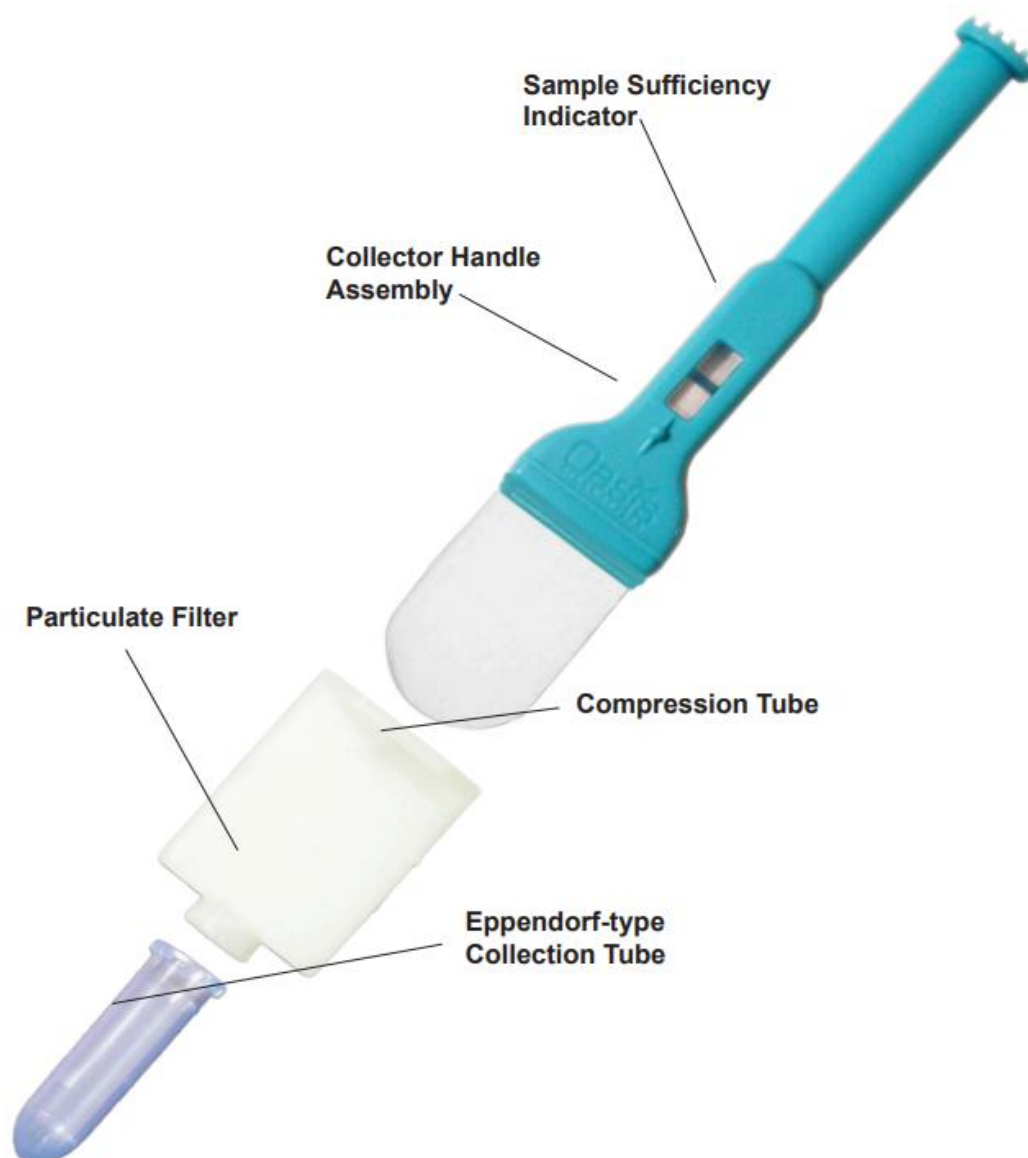


Versi-SAL™ Saliva Collection Kit

Catalogue number: SALV-011

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



Intended use

- The Versi-SAL™ Saliva Collection Kit is intended for the controlled, standardized collection and transportation of saliva (oral fluid) specimens for subsequent disease testing, analysis or research applications. The devices do not provide any diagnosis of disease.
- Non-invasive and easy to use with a Sample Volume Adequacy Indicator.
- Ideal for the easy collection of saliva samples for multiple applications (drug molecules, infectious diseases, cotinine, hormones, etc.)

Principles of the device

- The Versi-SAL™ Saliva Collection Kit is a proprietary, patented system intended for the standardized collection and purification of whole saliva (oral fluid), from under the tongue. In order to collect an adequate specimen, subjects / patients are requested to “pool” saliva under the tongue to facilitate faster collection times.
- The Versi-SAL™ device features an absorbent pad material, which is placed under the tongue to collect the sample.
- Versi-SAL™ incorporates a built-in Sample Volume Adequacy Indicator (SVAI), which ensures that enough saliva has been collected.

Materials provided

- Versi-SAL™ Saliva Collection Device with single absorbent collection pad and sample sufficiency indicator.
- Sample Compression Tube.

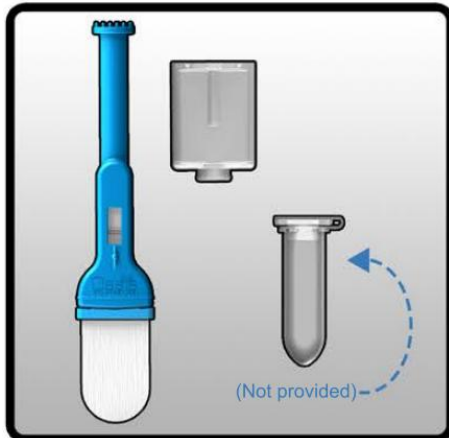
Instructions for use

- 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 eat, drink, smoke, or use oral hygiene products for at least 30 minutes before commencing the collection process.
- Versi-SAL™ incorporates a highly absorbent collection pad, which soaks up saliva very quickly and efficiently. In order to facilitate faster sample collection, remove the device from the mouth occasionally (approximately every 30 seconds), if required. Immediately observe the Sample Volume Adequacy Indicator while “pooling” further saliva under the tongue, then promptly replace the Versi-SAL™ device under the tongue and resume collecting saliva until the Sample Volume Adequacy Indicator changes, signifying sufficient saliva sample has been collected.

Step by step instructions

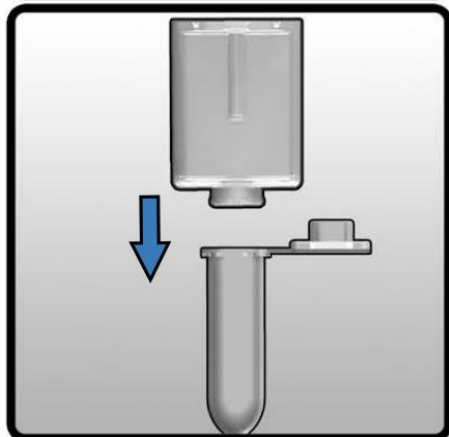
- Ensure collection is continued until the Sample Volume Adequacy Indicator visually changes, confirming sample sufficiency.

1.



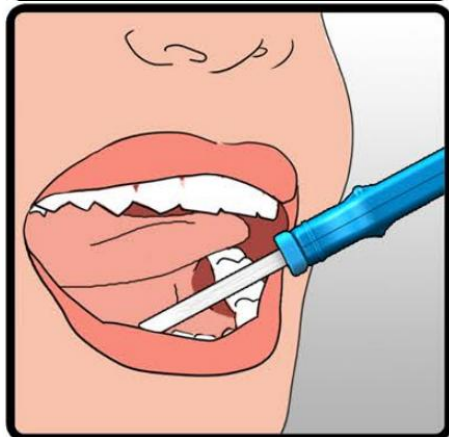
Open the package and place the contents on a clean and dry surface.

2.



Attach a standard 2 mL graduated Eppendorf Tube to the outlet of the Compression Tube provided. Ask the subject to "pool" saliva in the mouth, under the tongue.

3.



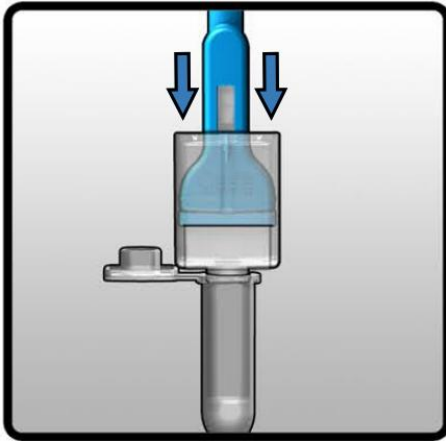
Take the Versi-SAL™ device by the handle and place the Absorbent Pad under the tongue to collect saliva until the Sample Volume Adequacy Indicator (SVAI) changes. Sample collection may take between 1-3 minutes.

4.



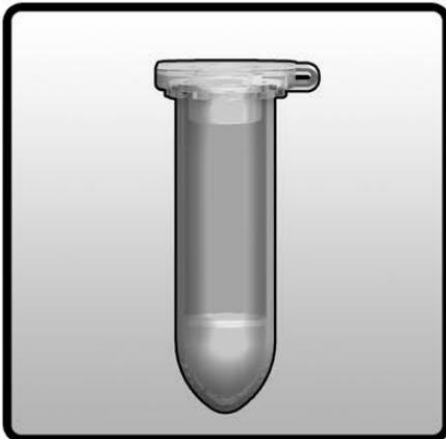
Periodically (every 30 seconds) remove the device from the mouth and view the Sample Volume Adequacy Indicator (SVAI). When the visible line is no longer in the viewing window (right side image), collection is complete.

5.



Holding the Versi-SAL™ device in an upright vertical position, push the Versi-SAL™ device down into the Compression Tube with your other hand. Continue compression until saliva has stopped flowing from the Absorbent Pad.

6.



Saliva will flow from the Absorbent Pad into the Eppendorf Tube. Once no more compression is possible allow 30 additional seconds for sample to drain into the Eppendorf Tube. Remove the Tube and seal Cap firmly.

7.



Process the collected sample immediately or store for future analysis, according to the requirements of the analyte(s) to be tested. If the sample is to be analysed remotely, place the sealed Eppendorf tube into a suitable transport container.

8.



The sample is now ready for transportation to the laboratory.

Precautions and notes

- DO NOT DRINK 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.
- Collect until the Sample Volume Adequacy Indicator (SVAI) provides a visual indication that the required volume has been collected (visible line disappears). Typical collection time is 1–3 minutes. If the requisite sample has failed to collect within 15 minutes discard the device and begin a further collection with a fresh device. Note: The length of time for collection and the quantity of saliva collected will vary between individuals due to inherent differences in saliva viscosity, hydration levels and medical conditions such as dry mouth.
- As an option, saliva (oral fluids) may be removed from the Versi-SAL™ Saliva Collection Device by vortexing or centrifugation.
- The absorbent material used to collect specimens contains no added salts, preservatives or other agents.
- Analysis of whole saliva collected using the Versi-SAL™ Saliva Collection Kit should be done according to validated protocols according to assay requirements.
- Salvivo Limited and Oasis Diagnostics® Corporation provide no warranty as to the suitability of the Versi-SAL™ Saliva Collection Kit, for any given application, other than the Intended Use described herein.
- Versi-SAL™ Saliva Collection Kits 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 Versi-SAL™ Saliva Collection Kit does not diagnose any disease.

Ordering information

- Versi-SAL™ Saliva Collection Kits are sold in units of 50 kits per box and 10 boxes (500 kits) per case. Please contact Salvivo Limited 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 Limited via the contact details below.



SALVIVO LIMITED
The Stamp Exchange
Westgate Road
Newcastle upon Tyne, NE1 1SA
United Kingdom

web: www.salvivo.com

email: info@salvivo.com