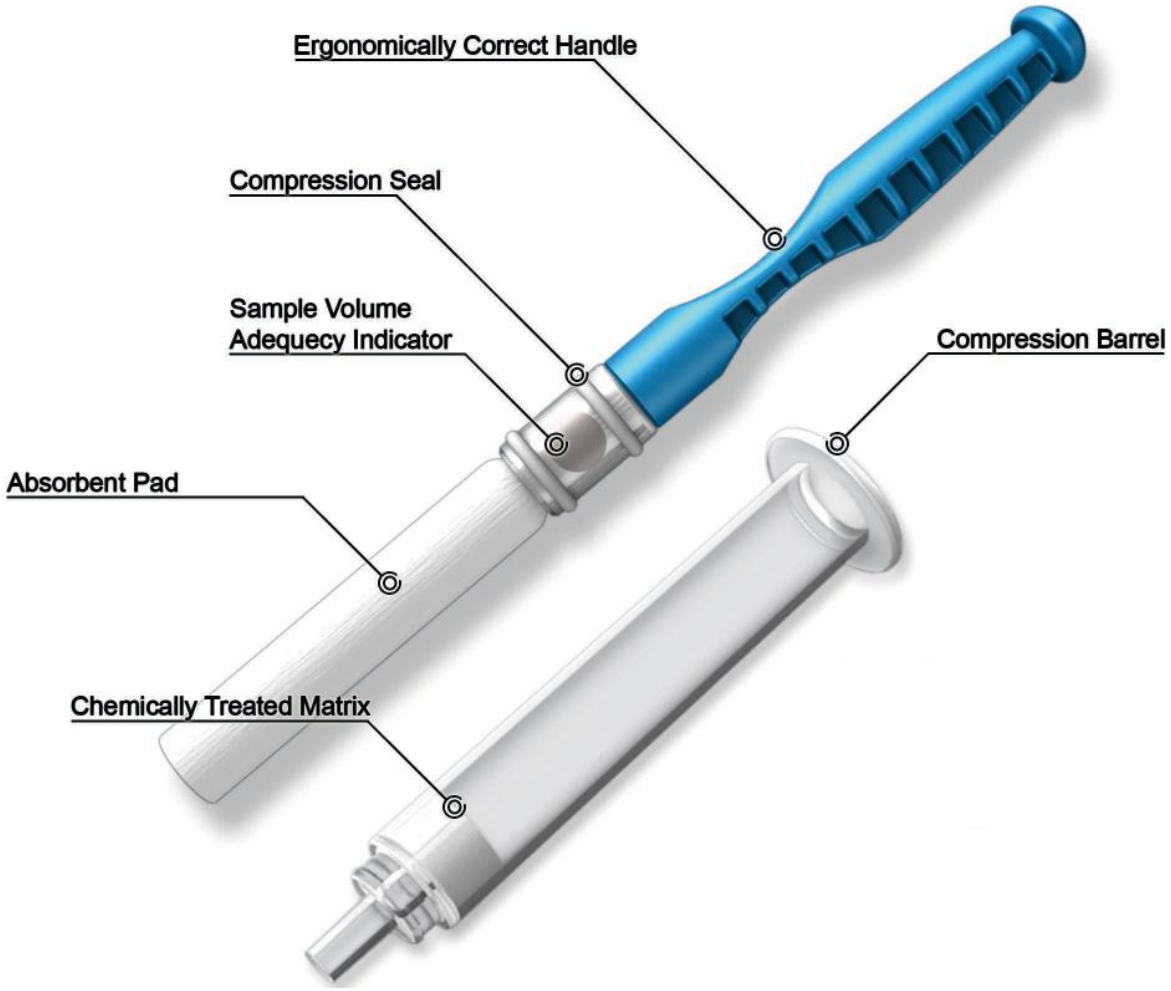
Pure-SAL™ Universal Saliva Collection Kit

Catalogue number: SALV-005

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



Intended use

- The Pure-SAL™ Universal Saliva Collection Kit is intended for the controlled, standardised collection and transportation of saliva (oral fluid) specimens for subsequent testing, analysis, or research applications. The kits do not provide any diagnosis of disease.
- High volume liquid sample collection in 1-5 minutes.
- Contains a proprietary filtration matrix to exclude cells, mucins and other interference.
- Provides a sample that is rich in cell-free DNA, cell-free RNA, exosomes and proteins.
- Absorbent pad dimensions: length 52 mm, diameter 10 mm.
- Approximate maximum saliva collection volume: 1.5 mL.
- Ideal for the collection of RNA or proteins.

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Principles of the device

- The Pure-SAL™ Universal Saliva Collection Kit is a proprietary, patented system intended for the standardized collection and purification of whole saliva (oral fluid) using a proprietary built-in filtration system.
- Pure-SAL™ incorporates a built-in Sample Volume Adequacy Indicator (SVAI), which ensures that enough saliva has been collected. In order to collect an adequate specimen, subjects are requested to pool saliva in the mouth (under the tongue) to facilitate faster collection times.
- The Pure-SAL™ features a cylindrical absorbent pad that facilitates easy and rapid sample collection. Saliva is expressed from the absorbent pad through a compression tube into a standard Eppendorf tube.

Materials provided

- Pure-SAL™ Universal Saliva Collector.
- Compression Tube.
- 2.0 mL Eppendorf Tube.

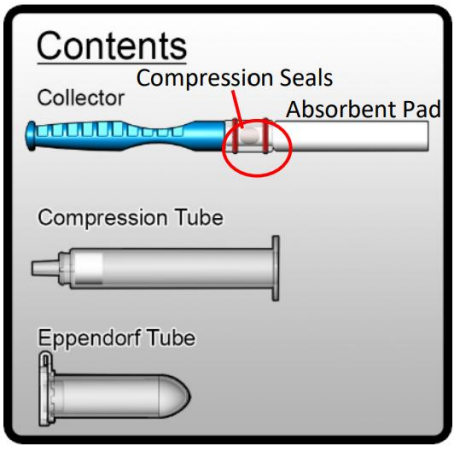
Instructions for use

- 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, particularly the illustrations showing the appearance of the Sample Volume Adequacy Indicator (SVAI) changing from white to fully red after sample collection.
- Do not eat, drink, smoke, or use oral hygiene products for at least 10 minutes before commencing the collection process.

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.

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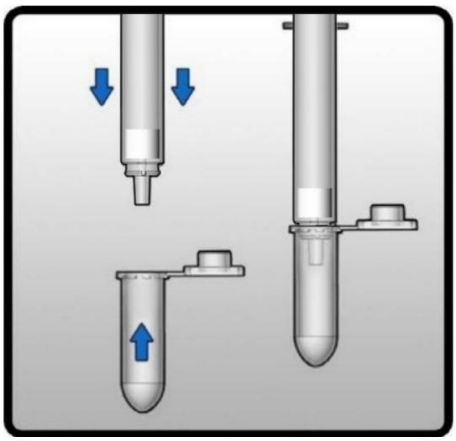
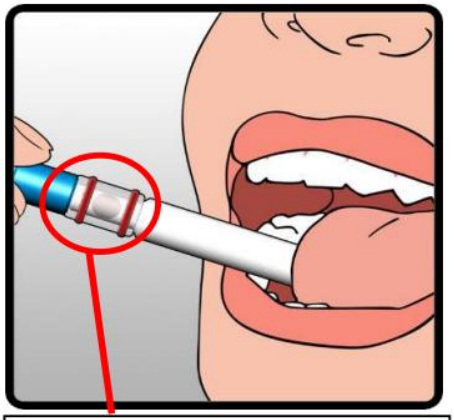
2.



Firmly attach the Eppendorf Tube provided to the base of the Compression Tube. In preparation for saliva collection, pool saliva in the mouth. Sample collection may now begin.

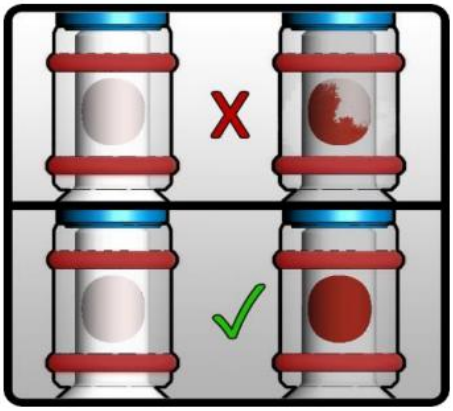
3.



Sample Volume Adequacy Indicator

Place the tip of the Absorbent Pad of the Collector under the tongue where saliva has pooled. The Collector may be removed from the mouth periodically to read the SVAI but resume collection immediately afterward.

4.

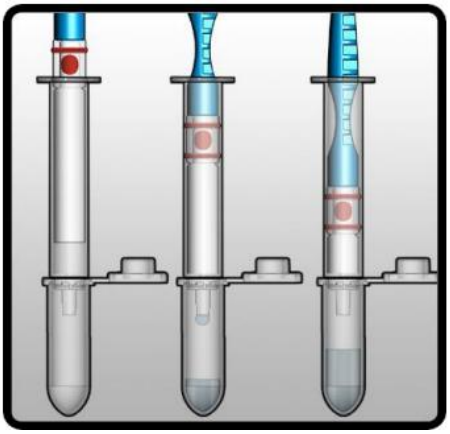


Collect until the appearance of the SVAI changes to fully red

OR

after having collected for 5 minutes (whichever occurs first).
The collection procedure should last approximately 1 minute to a maximum of 5 minutes.

5.



Place the Absorbent Pad end into the Compression Tube holding the Collector in an upright and vertical position. Firmly push the plunger downwards to transfer saliva from the Absorbent Pad into the Eppendorf Tube. Push and hold for 30 seconds.

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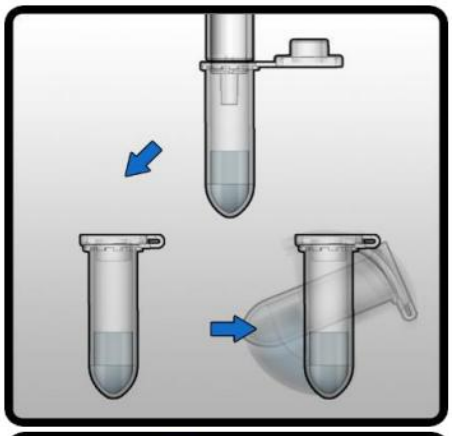
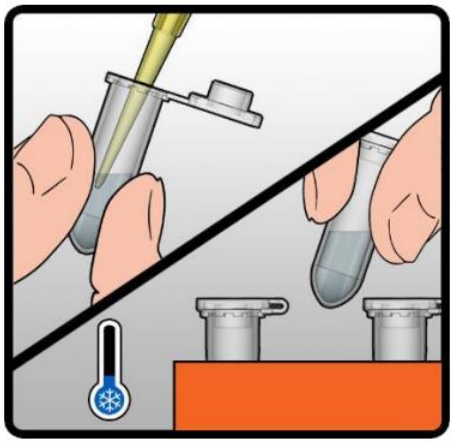
6. 

Gently remove the Eppendorf Tube from the end of the Compression Tube. It is appropriate to remove the Eppendorf Tube during expression if necessary due to foaming. Add stabiliser/preservative (not provided) if required and close the lid on the tube tightly. Close the lid tightly and invert the tube 2-3 times.

7. 

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 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) turns fully red. Typical collection time is 1–5 minutes. The maximum time for collection is 5 minutes in the mouth, after which you should express the sample to see if adequate volume has been collected to perform the test. If not, discard the Collector and begin a further collection with a fresh kit. 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.
- The absorbent material used to collect specimens contains no added salts, preservatives or other agents.
- Analysis of whole saliva collected using the Pure-SAL™ Universal Saliva Collection Kit should be done according to validated protocols according to assay requirements.

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- Salvivo Limited and Oasis Diagnostics® Corporation provide no warranty as to the suitability of the Pure-SAL™ Universal Saliva Collection Kit, for any given application, other than the Intended Use described herein.
- Pure-SAL™ Universal 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 Pure-SAL™ Universal Saliva Collection Kit does not diagnose any disease.

Ordering information

- Pure-SAL™ Universal 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.

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