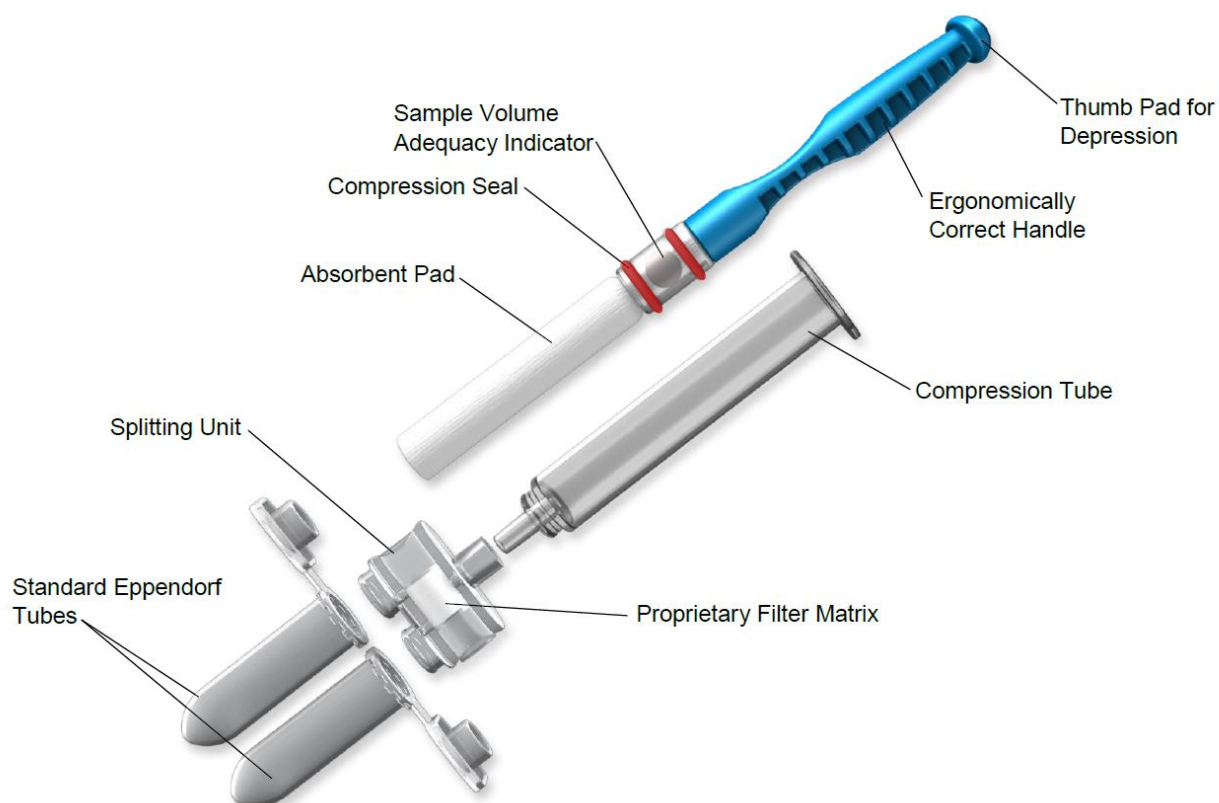


RNAPro-SAL™ Split Sample Saliva Collection Kit

Catalogue number: SALV-007

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



Intended use

- The RNAPro-SAL™ Split Sample Saliva Collection Kit is intended for the controlled and standardized collection of saliva (oral fluid) specimens and the simultaneous separation of cell-free RNA [miRNA and mRNA], cell-free DNA, exosomes, and proteins for subsequent stabilization and analysis in life sciences and research applications. The kits do not provide any diagnosis of disease.
- 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
- Cell free sample, with total sample volume of ~1.0 mL split between the two tubes.
- Simultaneous proteomic and transcriptomic isolation, amenable to extracellular RNA, and DNA, exosomes, and proteomics research.
- Ideal for the collection of RNA and proteins, utilising the advantage of the sample being expressed into two separate Eppendorfs.

Principles of the device

- The RNAPro-SAL™ Split Sample Saliva Collection Kit is a proprietary patented device intended for the standardized collection of highly purified saliva.
- In order to collect an adequate specimen, subjects are requested to pool saliva in the mouth, immediately prior to collection, to facilitate faster collection times.
- The specimen collected using the RNAPro-SAL™ Collection Kit is subsequently purified by compressing the sample through a small splitting unit containing a proprietary filtration matrix that removes various interferants. The sample is channelled into two standard collection tubes which may be used immediately or stabilized independently for storage and future use.

Materials provided

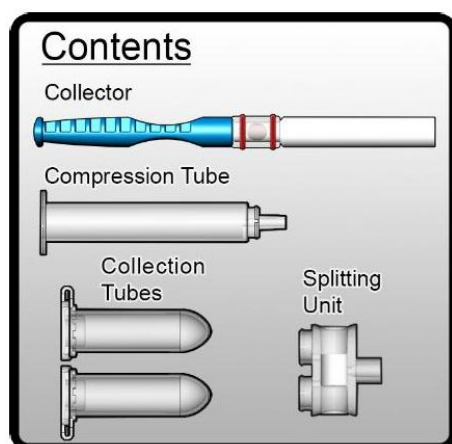
- RNAPro-SAL™ Collector.
- Single Compression Tube.
- Splitting Unit.
- Two standard 2.0mL Eppendorf Tubes.

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.

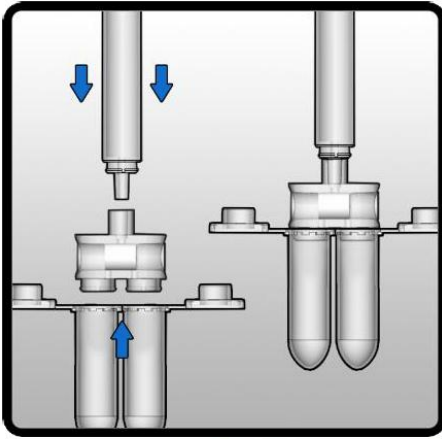
Step by step instructions

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



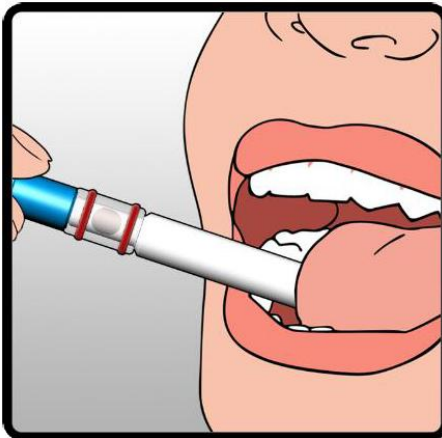
Open the package and place the contents on a clean and dry surface.

2.



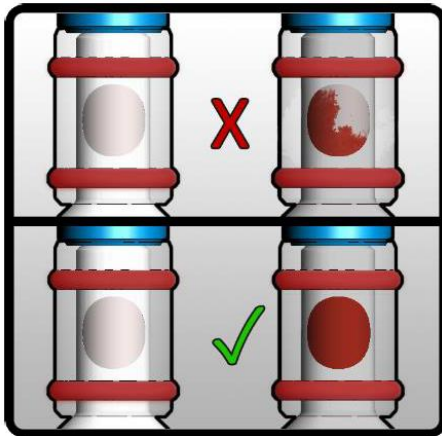
Attach the two Collection Tubes provided to the base of the Splitting Unit. Attach the Compression Tube into the top end of the Splitting Unit firmly. Sample collection may now begin.

3.



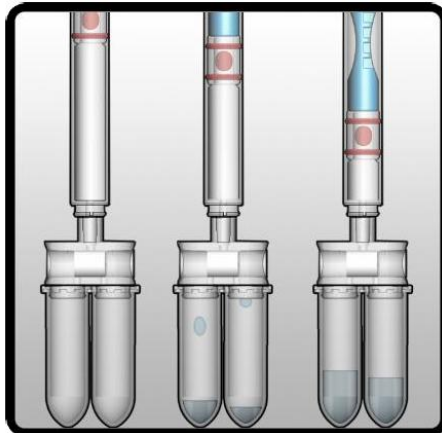
Place the tip of the pad of the Collector where saliva has pooled. The Collector may be removed from the mouth periodically to read the SVAI, but resume collection immediately afterward.

4.

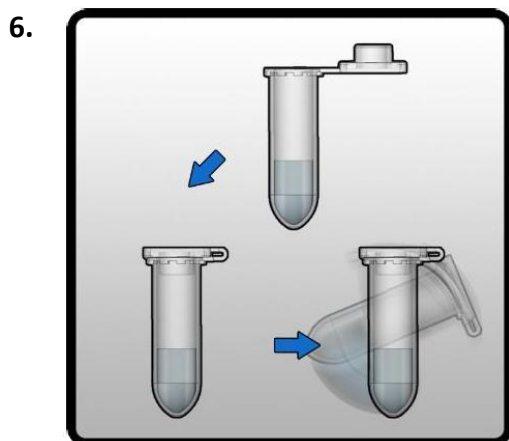


Collect until the appearance of the SVAI changes completely to red. The collection procedure should last approximately 1-5 minutes.

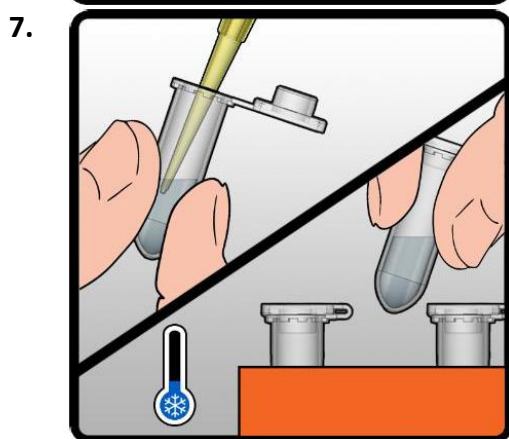
5.



Remove the Collector from the mouth and place the white absorbent pad end into the Compression Tube, holding the Collector in an upright position, and firmly push the plunger downwards to transfer saliva from the absorbent pad into the Collection Tubes. Push and hold for 30 seconds.



Gently remove the Eppendorf Tubes from the end of the Splitting Unit. Add preservative or stabilising agent for RNA/proteins (not provided), if required, and close the lids on each of the tubes tightly. Invert one of the tubes 2-3 times. Repeat operation for the second tube.



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 Tubes.
- 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. If the SVAI has failed to indicate within 15 minutes, express to see if adequate sample has been collected. 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.
- Stabilisation and analysis of samples collected using the RNAPro-SAL™ Split Sample 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 RNAPro-SAL™ Split Sample Kit for Liquid Biopsy, for any given application, other than the Intended Use described herein.
- RNAPro-SAL™ Split Sample Kits for Liquid Biopsy 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 RNAPro-SAL™ Split Sample Saliva Collection Kit does not diagnose any disease.

Ordering information

- RNAPro-SAL™ Split Sample Kits for Liquid Biopsy 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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