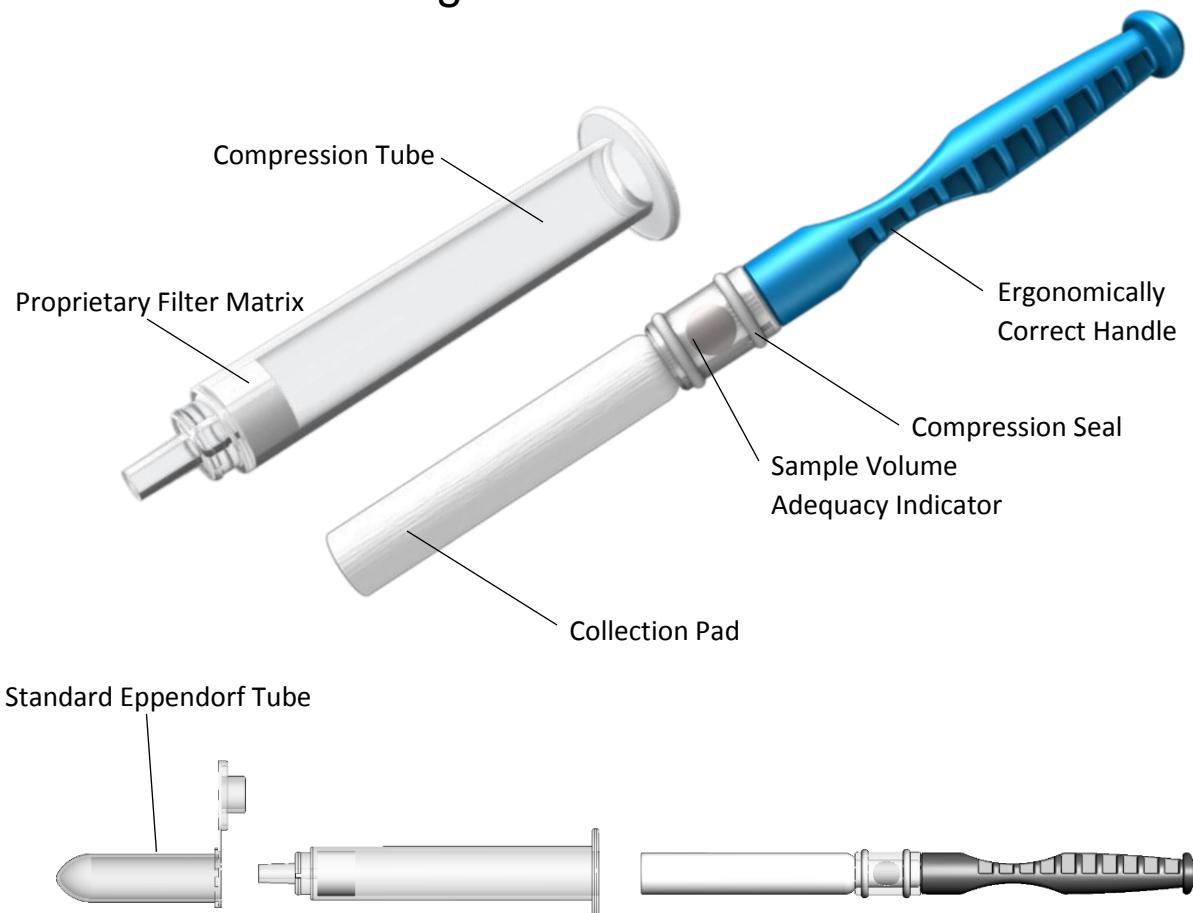


Pure•SAL™

SALIVA PURIFICATION for LIQUID BIOPSY

Catalog Number: PRSAL-401



Intended Use

The Pure•SAL™ Saliva Purification Kit for Liquid Biopsy is intended for the controlled and standardized collection of oral fluid specimens, including cell-free RNA [miRNA and mRNA], cell-free DNA, exosomes, or proteins, for subsequent stabilization and analysis in life science and research applications. The Pure•SAL™ does not provide any diagnosis of disease.

For research use only in the United States. The performance characteristics of this device have not been evaluated by the FDA.

Introduction

Nucleic Acid Testing (NAT) and proteomics research has largely been based on the use of traditional specimens such as blood and tissue, which have also been the most useful specimens for the development of functional diagnostic tests. Recent advances in salivary diagnostics research has produced several new and non-invasive options for the isolation of cell-free RNA (cfRNA), cell-free DNA (cfDNA), exosomes, and proteins. As a result, there has been a rapid uptake in the isolation and use of saliva for multiple applications.

Up until now, the direct isolation of cfRNA from saliva has proven difficult due to a number of interfering factors, particularly cells and cellular DNA, in saliva specimens.

The Pure•SAL™ Saliva Purification Kit for Liquid Biopsy provides a simple non-invasive and rapid platform for isolating cfRNA, cfDNA, exosomes, or proteins in a single step. The harvested, purified saliva specimen can be immediately stabilized and available for downstream PCR, genotyping, sequencing, proteomics, exosome precipitations and other applications.

Principles of the Device

The Pure•SAL™ Saliva Purification Kit for Liquid Biopsy is a proprietary patented system 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 Pure•SAL™ Collection Kit is subsequently purified by compressing the Collector through a Compression Tube which contains a proprietary filtration medium that removes various interferants. The sample is expressed into a standard Eppendorf Tube. The sample may be used immediately, or stabilized independently for storage, depending on the application.

Materials Provided

1. Pure•SAL™ Saliva Collector
2. Single Compression Tube with proprietary filter matrix
3. One Standard 2.0mL Eppendorf Tube

Materials Recommended but Not Provided

1. Timer
2. Stabilization Reagent for RNA (Catalog Number RDS-101)
3. Stabilizing Reagent for Protein Stabilization (Catalog Number PSS-001)
4. Tube Rack (Catalog Number TRAC-001, optional).

Instructions for Use

PLEASE READ THE COMPLETE INSTRUCTIONS BEFORE PROCEEDING TO COLLECT ORAL FLUIDS / SALIVA USING THE PURE•SAL™ SALIVA PURIFICATION KIT FOR LIQUID BIOPSY. FAILURE TO FOLLOW THESE INSTRUCTIONS CAREFULLY COULD PRODUCE LESS THAN SATISFACTORY RESULTS.

Do not eat, drink, smoke, or use oral hygiene products for at least 30 minutes before you start the collection process.

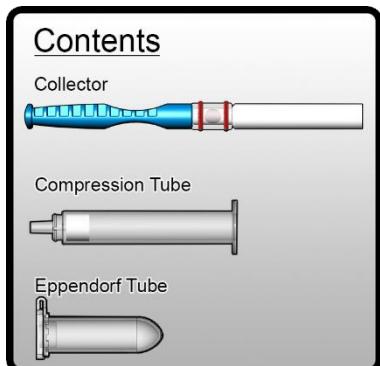
Prior to collection, review the detailed instructions on the Pure•SAL™ Saliva Purification Kit for Liquid Biopsy insert below, particularly the illustrations showing the appearance of the Sample Volume Adequacy Indicator (SVAI) changing from white to **fully** red after sample collection (Figure 4 below).

Step-by-Step Instructions

General Note:

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

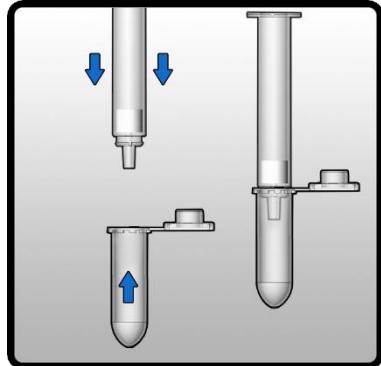
1.



Video instructions are available on our website at: 4saliva.com/products/pure-sal/

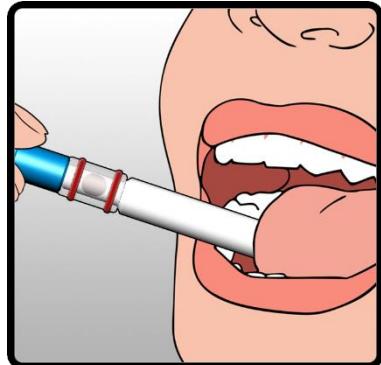
Place contents on a clean and dry surface. In preparation for saliva collection, **pool saliva** in the mouth.

2.



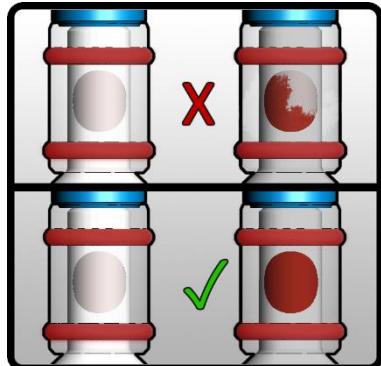
Attach the Eppendorf tube provided to the base of the Compression Tube firmly. Sample collection may now begin.

3.



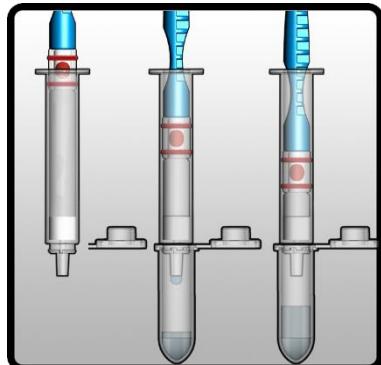
Place the tip of the pad of the Collector where saliva has pooled. The Collector may be removed from the mouth periodically to read the SVAI, but resume collection immediately afterward.

4.



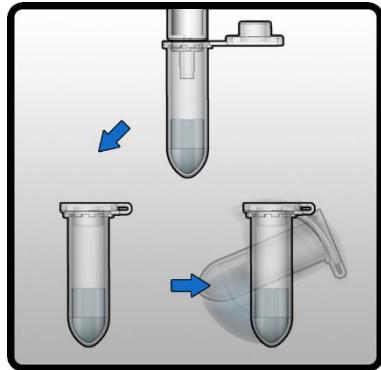
Collect until the appearance of the SVAI changes from white to fully red. The collection procedure should last approximately 1-5 minutes.

5.



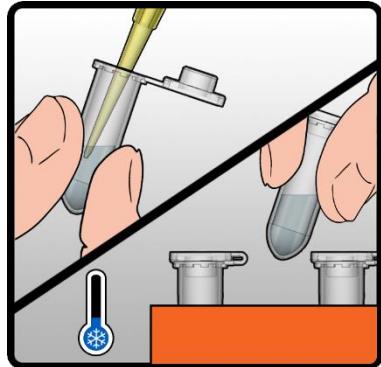
Place the white absorbent pad end into the Compression Tube, holding the Collector in an upright and vertical position, and firmly push the plunger downwards to transfer saliva from the absorbent pad into the Eppendorf Tube. Push and hold for 30 seconds.

6.



Gently remove the Eppendorf Tube from the end of the Compression Tube. Add preservative (not provided), if required, and close the lid tightly. Invert the tube 2-3 times.

7.



Process sample immediately or store at refrigerated temperatures (depending upon the specific application) until required.

Notes:

An optional Tube Rack (Catalog Number TRAC-001) from Oasis Diagnostics® helps maintain the Pure•SAL™ device in an upright position during sample acquisition.

Protein and RNA Stabilization Reagents are available from Oasis Diagnostics® Corporation. For advice on stabilization, please contact the company.

KIT COMPONENTS

Catalog Number	Item
PRSAL-401	Pure•SAL™ Saliva Purification Device for Liquid Biopsy
EPDF-201	Standard 2.0 mL Eppendorf Tube

Precautions and Notes

1. DO NOT DRINK WHILE COLLECTION IS IN PROGRESS
2. DO NOT REUSE OR SUBSTITUTE DEVICE COMPONENTS

3. Kits are for single use only. Used Collectors and samples should be treated as potentially infectious and disposed of in accordance with current regulations.
4. Do not use kits beyond the expiration date printed on the pouch.
5. Prior to use, record subject information on the Eppendorf Tube.
6. During sample collection, ensure that the subject does not chew or suck on the absorbent collection pad.
7. Collect until the Sample Volume Adequacy Indicator (SVAI) provides a visual indication that the required volume has been collected. 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.

8. As an option, for increased yields, continue to collect for an additional 1 minute after the SVAI visual color change.
9. The absorbent material used to collect specimens contains no added salts, preservatives or other agents.
10. Stabilization of saliva samples to protect RNA and/or proteins and testing of oral fluids collected using the Pure•SAL™ Saliva Purification Kit for Liquid Biopsy should be done according to validated protocols provided by kit manufacturers. Oasis Diagnostics® Corporation provides no warranty as to the suitability of the Pure•SAL™ Saliva Purification Kit for Liquid Biopsy, for any given application, other than the Intended Use described herein.
11. Pure•SAL™ Saliva Purification Kits for Liquid Biopsy are provided in clean, non-sterile form, but may be provided in sterile form upon request.
12. Store at room temperature (15-30°C) until the expiration date written on the exterior of the pouch.
13. The Pure•SAL™ Saliva Purification Kit for Liquid Biopsy does not diagnose any disease.

Ordering Information

Pure•SAL™ Saliva Purification Kits for Liquid Biopsy are sold in units of 50 collection kits per box and 8 boxes (400 kits) per shipping case (see Ordering Information below).

Kit Components

Pure•SAL™ Saliva Purification Kit for Liquid Biopsy

Catalog Number: PRSAL-401

Qty: 50/400

Additional Components

Tube Rack

Catalog Number: TRAC-001

Qty: 1

Standard 2.0 mL Eppendorf Tubes

Catalog Number: EPDF-201

Qty: 50/500

Protein Stabilizing Reagent

Catalog Number: PSS-001

Qty: 1 Bottle (enough stabilizing reagent for 50 kits)

RNA Stabilizing Reagent

Catalog Number: RDS-101

Qty: 1 Bottle (enough stabilizing reagent for 50 kits)

Final Note

Pure•SAL™ Saliva Purification Devices for Liquid Biopsy are available in different custom formats depending upon the required application. Please contact Oasis Diagnostics® Corporation for further details.

Manufactured for Oasis Diagnostics® Corporation in the United States

This device is protected by US and EU Patents including US Patent Numbers

7,618,591

7,927,548

8,273,305 and others

Rev: 20170510

TECHNICAL SUPPORT

For Technical Support [available between 8.00 a.m. and 5.00 p.m. Pacific Standard Time] Monday through Friday, please call Oasis Diagnostics® Corporation at (360) 546-1563.

Technical support may also be obtained by sending details of any requirements by contacting:



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