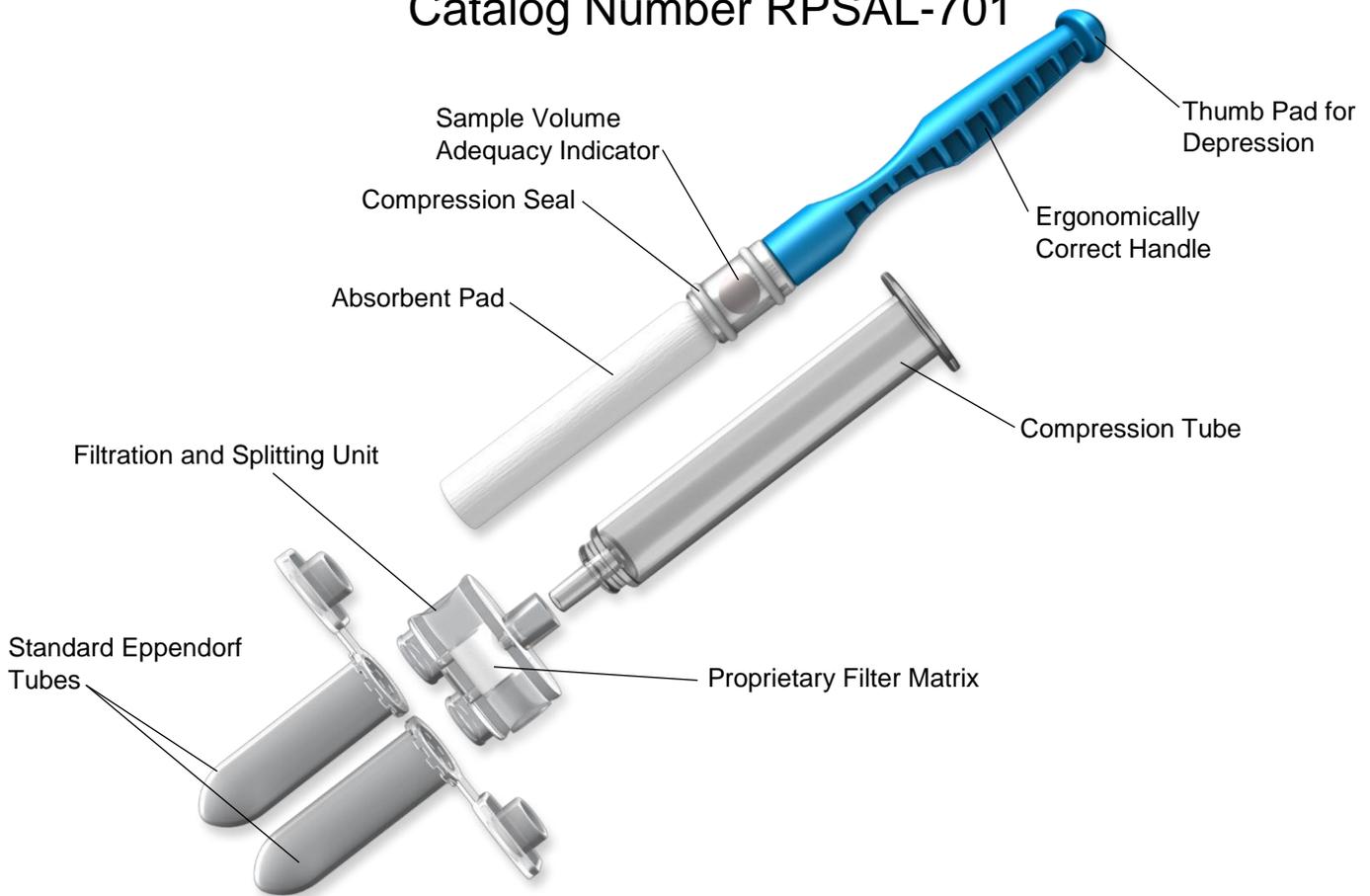


RNAPro•SAL™

SPLIT SAMPLE FOR LIQUID BIOPSY

Catalog Number RPSAL-701



Intended Use

The RNAPro•SAL™ Split Sample Kit for Liquid Biopsy is intended for the controlled and standardized collection of 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 science and research applications. The RNAPro•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 have 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 RNA from saliva has proven difficult due to a number of interfering factors, particularly cells and cellular DNA, in saliva specimens.

The RNAPro•SAL™ Split Sample Device for Liquid Biopsy provides a simple non-invasive and rapid platform for isolating cfRNA, cfDNA, exosomes, and proteins in a single step. Protein and cfRNA fractions are immediately stabilized and available for downstream PCR, genotyping, sequencing, proteomics, exosome precipitations, and other applications.

Principles of the Device

The RNAPro•SAL™ Split Sample Device for Liquid Biopsy 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 Device is subsequently purified by compressing the sample through a small splitting unit containing a proprietary filtration matrix that removes various interferants. The sample is channeled into two standard collection tubes which may be used immediately or stabilized independently for storage and future use.

Materials Provided

1. RNAPro•SAL™ Collector
2. Single Compression Tube
3. Filtration and Splitting Unit
4. Two Standard 2.0mL Eppendorf Tubes

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)

Instructions for Use

PLEASE READ THE COMPLETE INSTRUCTIONS BEFORE PROCEEDING TO COLLECT ORAL FLUIDS / SALIVA USING THE RNAPRO•SAL™ SPLIT SAMPLE 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 10 minutes before you start the collection process.

Rinse the mouth with water and discard. Please wait at least 5 minutes after this rinse to start the collection procedure.

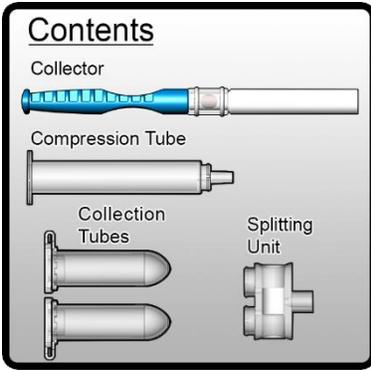
During this time review the detailed instructions on the RNAPro•SAL™ Split Sample Kit for Liquid Biopsy insert below, particularly the illustrations showing the appearance of the Sample Volume Adequacy Indicator (SVAI) changing from white to **fully** red after sample collection (Figure 4 below).

Step-by-Step Instructions

General Note:

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

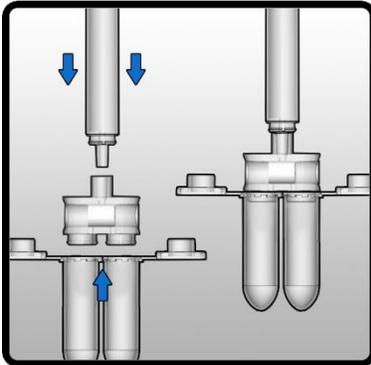
1.



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

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

2.



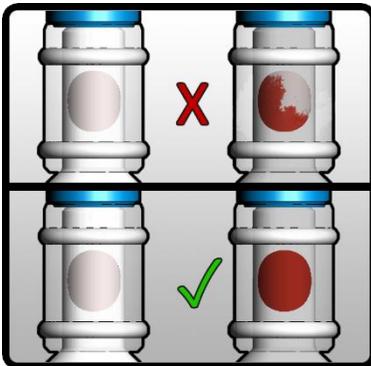
Attach the two Collection Tubes provided to the base of the Splitting Unit. Attach the Compression Tube into the top end of the Splitting Unit firmly. Sample collection may now begin.

3.



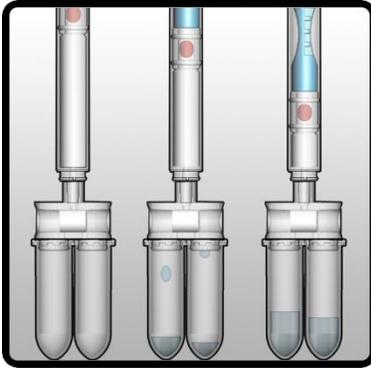
Place the tip of the pad of the Collector where saliva has pooled. The Collector may be removed from the mouth periodically to read the SVAI, but resume collection immediately afterward.

4.



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

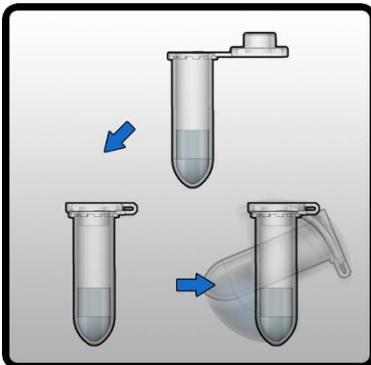
5.



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.

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

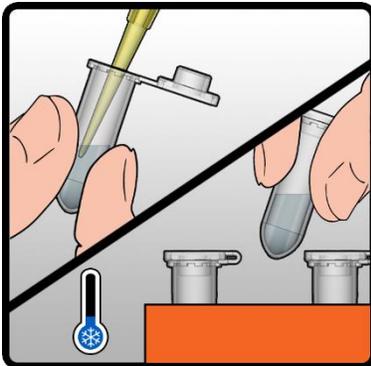
6.



Gently remove the Eppendorf Tubes from the end of the Splitting Unit. Add preservative (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.

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

7.



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

KIT COMPONENTS

<u>Catalog Number</u>	<u>Item</u>
RPSAL-701	RNAPro•SAL™ Collector (with Compression Tube and Splitting Unit)
EPDF-201	2x Standard 2.0 mL Eppendorf Tubes

Precautions and Notes

1. DO NOT DRINK WHILE COLLECTION IS IN PROGRESS
2. DO NOT REUSE OR SUBSTITUTE KIT 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 patient / subject information on each of the Eppendorf Tubes.
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 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, oral fluids (saliva) may be removed from the RNAPro•SAL™ Collector by centrifugation.
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 testing of oral fluids collected using the RNAPro•SAL™ Split Sample 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 RNAPro•SAL™ Split Sample Kit for Liquid Biopsy, for any given application, other than the Intended Use described herein.
11. RNAPro•SAL™ Split Sample 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 RNAPro•SAL™ Split Sample Kit for Liquid Biopsy 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 shipping box (see Ordering Information below).

Kit Components

RNAPro•SAL™ Split Sample Kit for Liquid Biopsy

Catalog Number: RPSAL-701

Qty: 50/500

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

RNAPro•SAL™ Split Sample Kits for Liquid Biopsy are available in different custom formats depending upon the required application. Please contact Oasis Diagnostics® 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: 20170503

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 e-mail to info@4saliva.com.



Oasis Diagnostics® Corporation

15720 NE 31st Avenue

Vancouver WA 98686 USA

Phone: (360) 546-1563

FAX: (360) 546-1581

Website: www.4saliva.com

E-mail: info@4saliva.com