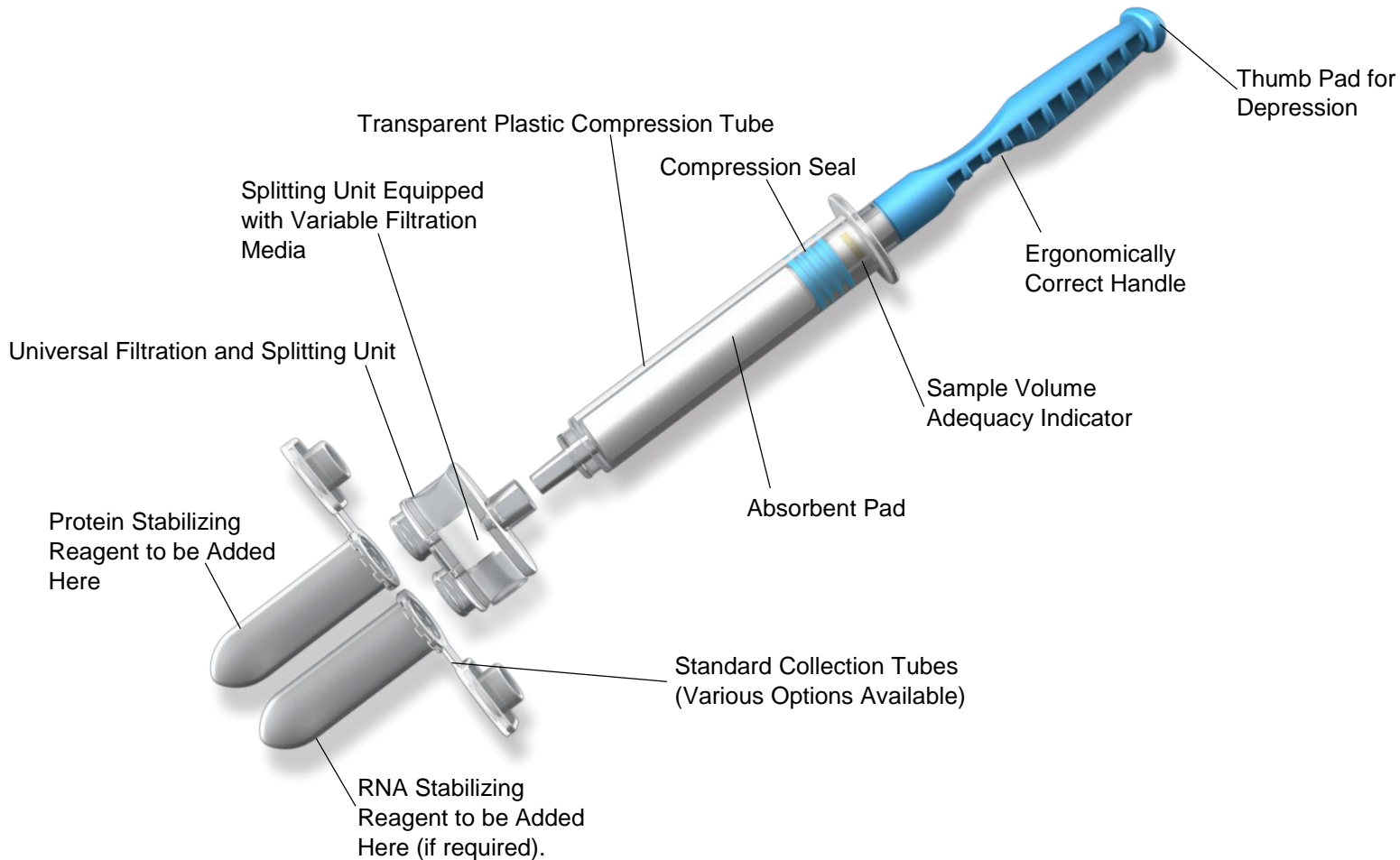


RNAPro•SAL™

ORAL SPECIMEN COLLECTION SYSTEM

Catalog Number RPSAL-701



Intended Use

The RNAPro•SAL™ Oral Specimen Collection System is intended for the controlled and standardized collection of oral fluid specimens and the simultaneous separation of RNA, DNA, 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 has produced several new and non-invasive options for the isolation of DNA and proteins and 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 DNA, in saliva specimens.

The RNAPro•SAL™ Oral Specimen Collection System provides a simple non-invasive and rapid platform for isolating DNA / cell free RNA and proteins in a single step. Protein and RNA fractions are immediately stabilized and available for downstream PCR, genotyping, sequencing, proteomics and other applications.

Principles of the Device

The RNAPro•SAL™ Oral Specimen Collection System is a proprietary patented device intended for the standardized collection of whole saliva from along the inside of the tongue adjacent to the gum line.

In order to collect an adequate specimen subjects/patients 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 medium that removes various interferants. The sample is channeled into two standard collection tubes and each of the two samples is stabilized independently and may be used immediately or stored for long periods of time pending analysis.

Materials Provided

1. RNAPro•SAL™ Saliva Collection Device.
2. Transparent Plastic Compression Tube.
3. Universal Filtration and Splitting Unit.

4. Two Standard Collection Tubes (several options available).
5. Dropper Bottle Containing Stabilization Reagent for Protein Stabilization (X mL)

Materials Required but not Provided

1. Timer
2. Stabilization Reagent for RNA (available from multiple manufacturers)
3. Tube Rack (Catalog Number TRAC-001, optional).

Instructions for Use

PLEASE READ THE COMPLETE INSTRUCTIONS BEFORE PROCEEDING TO COLLECT ORAL FLUIDS / SALIVA USING THE RNAPro•SAL™ DEVICE. 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.

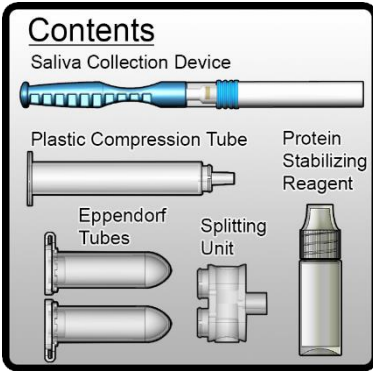
During this time review the detailed instructions on the RNAPro•SAL™ Oral Specimen Collection System insert below, particularly the illustrations showing the appearance of the Sample Volume Adequacy Indicator (SVAI) before and after sample collection [See figure 4 below].

Step-by-Step Instructions

General Note:

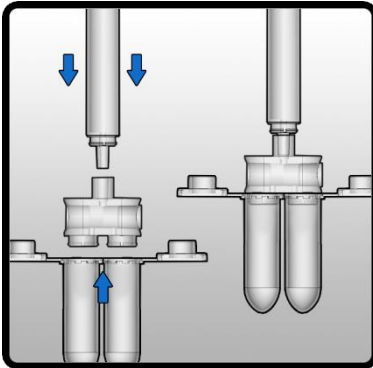
Ensure collection is continued until the Sample Volume Adequacy Indicator visually changes, confirming sample sufficiency. [Figure 4 below].

1.



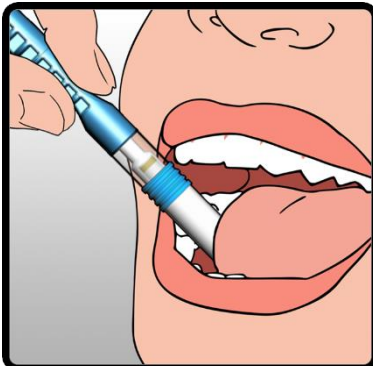
After the five minutes suggested at the beginning of this Instructions for Use section have passed, open the package containing the RNAPro-SAL™ Oral Specimen Collection System, being careful not to drop the contents on the floor. Place contents on a clean and dry surface. Make sure all of the components shown on the left are provided.

2.



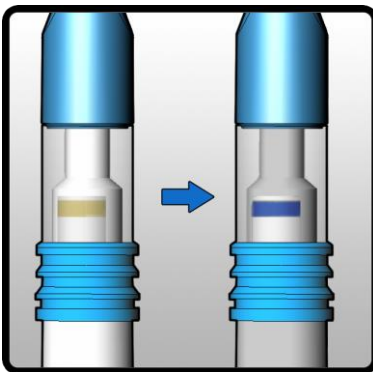
Attach the two Collection Tubes provided to the base of the Universal Filtration and Splitting Unit (“Splitting Unit”) as shown in Figure 2. Attach the Compression Tube into the top end of the Splitting Unit firmly (Figure 2). Sample collection may now begin. Pool saliva in the mouth as you prepare to take the sample.

3.



Place the white absorbent pad end of the device into the pool of saliva that has formed in the mouth, and collect until the appearance of the Sample Volume Adequacy Indicator [SVAI] changes from yellow [Figure 4, left-hand side], to blue [Figure 4, right-hand side].

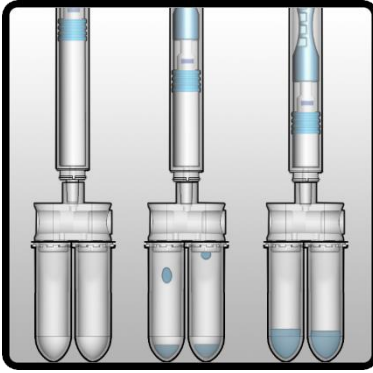
4.



Appearance of the Sample Volume Adequacy Indicator [SVAI] Left: Before Collection. Right: After Collection.

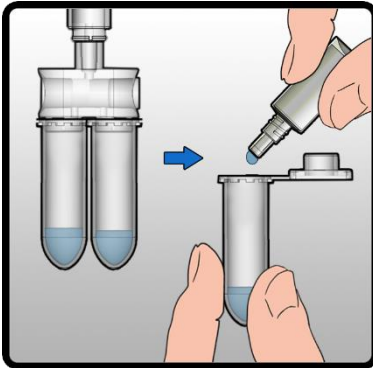
Note: It is appropriate to remove the device from the mouth periodically in order to read the SVAI, but immediately return the collection device to the mouth and resume collection. The collection procedure should last approximately 1-3 minutes.

5.



Remove the RNAPro•SAL™ device from the mouth and place the white absorbent pad end into the Compression Tube holding the RNAPro•SAL™ in an upright and vertical position and firmly push the plunger downwards to transfer saliva from the absorbent pad into the Cryofuge 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.

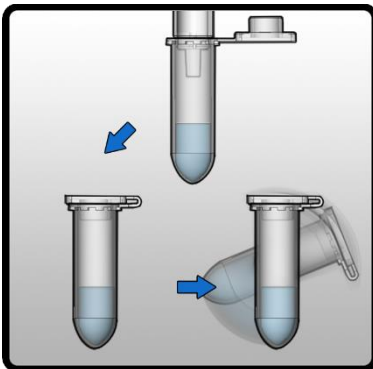
6.



Protein Stabilization

Gently remove one of the Microfuge Tubes from the end of the Plastic Compression Tube and add Protein Stabilizing Reagent from the dropper bottle provided. The number of drops required for stabilization may be calculated from the chart shown below, i.e. if 0.5 mL of saliva is collected, please add 5 drops of Protein Stabilizing Reagent. Close the lid on the tube tightly. Invert 2-3 times.

7.

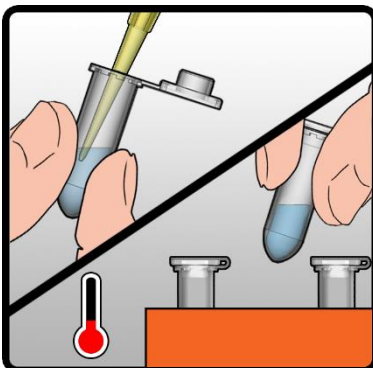


RNA Stabilization

Remove the second Collection Tube from the end of the Plastic Compression Tube. To stabilize the saliva sample for RNA add RNA stabilizing agent from a recognized commercial source according to the instructions provided by the manufacturer. NOTE: RNA Stabilizing Reagent is not provided and must be purchased separately. After addition close the lid on the tube tightly. Invert 2-3 times to mix the sample.

NOTE: If only RNA or Proteins is required, but not both, the two fractions of saliva may be combined prior to sample stabilization.

8.



Process the collected sample immediately or store at refrigerated temperatures [2-8°C or -20°C, depending upon the specific application] until required.

Protein Stabilization Chart

Saliva (μ l)	Drops to Add
100	1
200	2
300	3
400	4
500	5
600	6
700	7
800	8
900	9
1000	10

KIT COMPONENTS

<u>Catalog Number</u>	<u>Item</u>
RPSAL-701	RNAPro•SAL™ Universal Saliva Collection Device
MFGT-301	Standard 1.5 mL Microfuge Tubes
EPDF-201	Standard 2.0 mL Eppendorf Tubes
Note	The RNAPro•SAL™ may include either of the above collection tubes or other options for sample collection.

Precautions and Notes

1. DO NOT DRINK WHILE COLLECTION IS IN PROGRESS
2. DO NOT REUSE OR SUBSTITUTE DEVICE COMPONENTS
3. Devices are for single use only. Used devices and samples should be treated as potentially infectious and disposed of in appropriate biohazardous waste containers.
4. Do not use devices beyond the expiration date printed on the pouch.

5. Prior to use, record patient / subject information on each of the Microfuge Collection 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 – 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.
8. As an option, oral fluids (saliva) may be removed from the RNAPro•SAL™ Oral Specimen Collection System by vortexing or 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™ Oral Specimen Collection System 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™ Oral Specimen Collection System, for any given application, other than the Intended Use described herein.
11. RNAPro•SAL™ Oral Specimen Collection Systems are provided in 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™ Oral Specimen Collection System does not diagnose any disease.

Ordering Information

RNAPro•SAL™ Collection Devices are sold in units of 15 collection devices per box and 10 boxes (150 devices) per shipping box (see Ordering Information below).

RNAPro•SAL™ Oral Specimen Collection System

Catalog Number: RPSAL-701

Qty: 15

1.5 mL Microfuge Tubes

Catalog Number: MFGT-301

Qty: 100/500

Optional Component

Tube Rack

Catalog Number TRAC-001

Qty: 1

Final Note

RNAPro•SAL™ Devices are provided 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: 20160503

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.



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