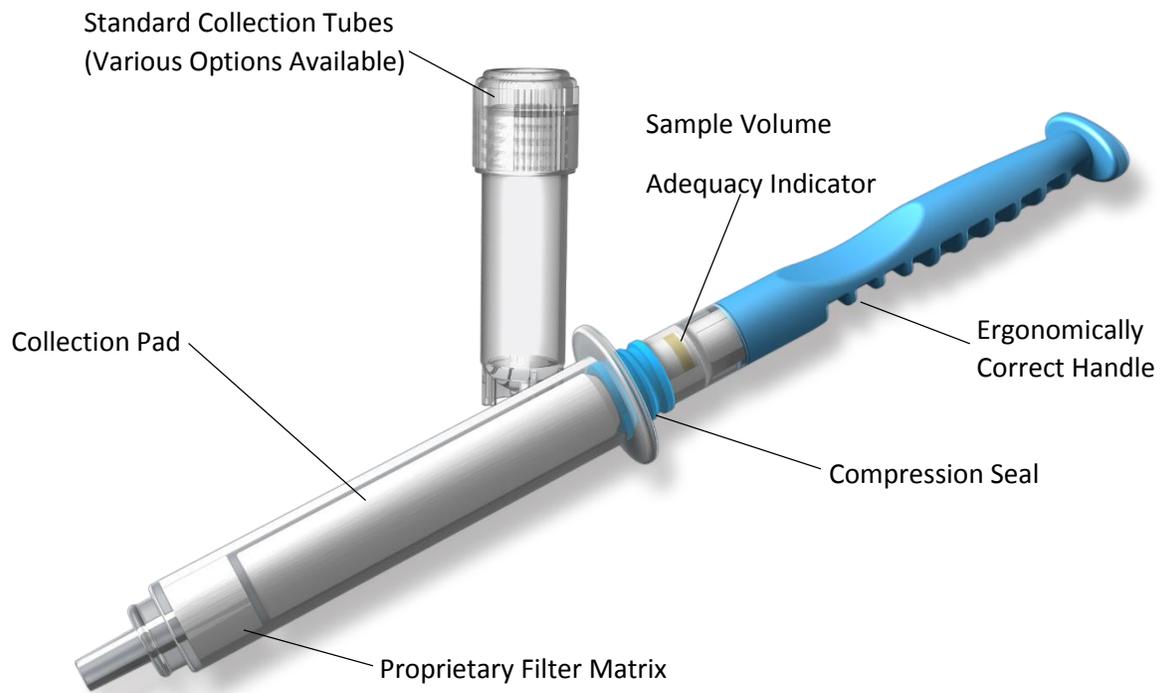


Pure•SAL™

ORAL SPECIMEN COLLECTION SYSTEM

Catalog Number PRSAL-401



Intended Use

The Pure•SAL™ Oral Specimen Collection System is intended for the controlled and standardized collection of oral fluid specimens RNA, DNA 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 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 Pure•SAL™ Oral Specimen Collection System provides a simple non-invasive and rapid platform for isolating virtually cell free RNA, DNA 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, depending upon your desired results.

Principles of the Device

The Pure•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 Pure•SAL™ Collection Device is subsequently purified by compressing the sample through the compression tube of the device containing a proprietary filtration medium that removes various interferants. The sample is directed into a standard collection tube and the sample is stabilized independently and may be used immediately or stored for long periods of time pending analysis.

Materials Provided

1. Pure•SAL™ Saliva Collection Device.
2. Transparent Plastic Compression Tube.
3. One Standard Collection Tube (several options available).

Materials Required but not Provided

1. Timer
2. Stabilization Reagent for RNA (available from multiple manufacturers)
3. Stabilizing Reagent for Protein Stabilization (available as an optional component from Oasis Diagnostics®)
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™ 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.

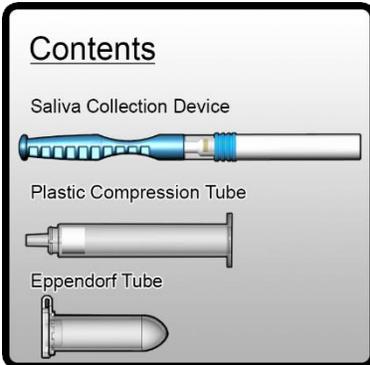
During this time review the detailed instructions on the Pure•SAL™ Oral Specimen Collection System insert below, particularly the illustrations showing the appearance of the Sample Volume Adequacy Indicator (SVAI) before and after sample collection [See figure 4 below].

Step-by-Step Instructions

General Note:

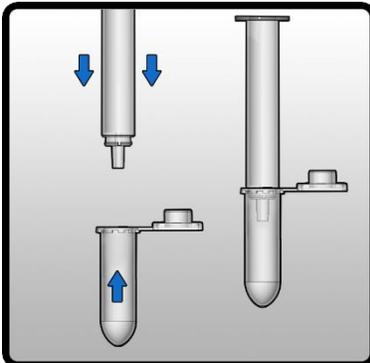
Ensure collection is continued until the Sample Volume Adequacy Indicator visually changes, confirming sample sufficiency. [Figure 5 below].

1.



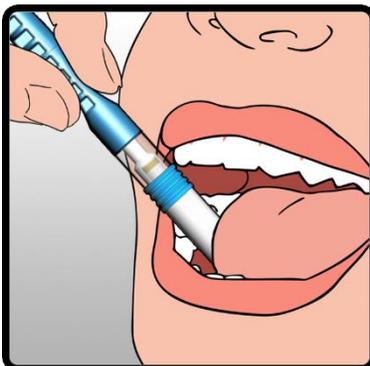
In preparation for oral fluid (saliva) collection place contents on a clean and dry surface away from any potential hazards which might contaminate components.

2.



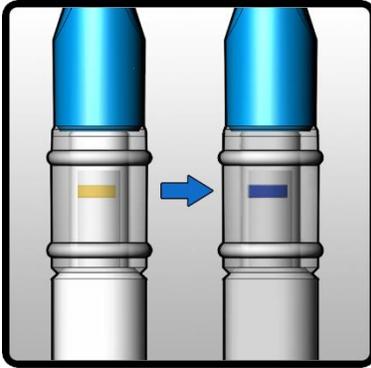
Attach the microfuge tube provided to the base of the Compression Tube. Sample collection may now begin. Pool saliva in the mouth as you prepare to take the sample.

3.



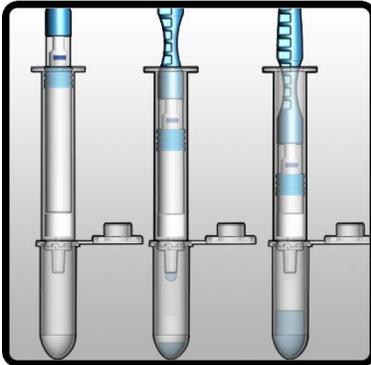
Place the tip of the white absorbent pad end of the device into the pool of saliva that has formed in the mouth. Allow saliva to wick up the pad. Collect until the appearance of the Sample Volume Adequacy Indicator [SVAI] changes from yellow to blue [see illustration 4].

4.



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

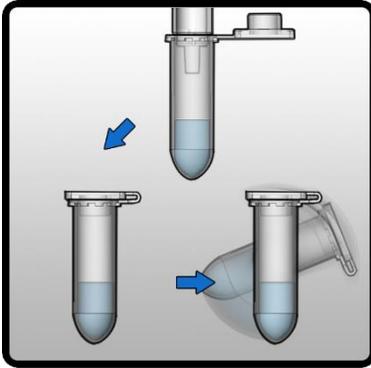
5.



Place the white absorbent pad end into the plastic Compression Tube holding the Pure•SAL™ in an upright and vertical position and firmly push the plunger downwards to transfer saliva from the absorbent pad into the microfuge tube. Push and hold for 30 seconds.

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

6.



Note: If samples are to be stored, add either Protein or RNA Stabilization Agents relevant to the proposed downstream application. Protein and RNA Stabilization Reagents are available from Oasis Diagnostics® Corporation. For advice on stabilization, please contact the company.

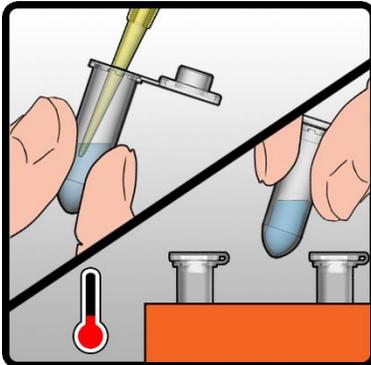
RNA Stabilization

Remove the Collection Tube from the end of the Plastic Compression Tube and cap firmly. To stabilize the saliva sample for RNA add RNA stabilizing agent. After addition, close the lid on the tube tightly. Invert 2-3 times to mix the sample

Protein Stabilization

Add Protein Stabilizing Reagent from the dropper bottle provided. The number of drops required for stabilization may be calculated from the chart shown below. For example, if 0.5 ml of saliva is collected, please add 7 drops of Protein Stabilizing Reagent. Close the lid on the tube tightly. Invert 2-3 times.

7.



Process sample immediately or store at refrigerated temperatures [depending upon the specific application] until required. For Technical Support, contact Oasis Diagnostics® at (360) 546-1563, or by e-mail to info@4saliva.com.

Protein Stabilization Chart

Saliva (μ l)	Drops to Add
70	1
140	2
210	3
280	4
350	5
420	6
490	7
560	8
630	9
700	10

KIT COMPONENTS

<u>Catalog Number</u>	<u>Item</u>
PRSAL-401	Pure•SAL™ Universal Saliva Collection Device
	Screw Cap (4.0 mL) Collection Tube

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 the Screw Cap Collection 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 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.

As an option, for increased yields, continue to collect for an additional 1 minute after the SVAI visual color change.

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. The absorbent material used to collect specimens contains no added salts, preservatives or other agents.
9. Stabilization of saliva samples to protect RNA and/or proteins and testing of oral fluids collected using the Pure•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 Pure•SAL™ Oral Specimen Collection System, for any given application, other than the Intended Use described herein.
10. Pure•SAL™ Oral Specimen Collection Systems are provided in non-sterile form but may be provided in sterile form upon request.
11. Store at room temperature (15-30°C) until the expiration date written on the exterior of the pouch.
12. The Pure•SAL™ Oral Specimen Collection System does not diagnose any disease.

Ordering Information

Pure•SAL™ Collection Devices are sold in units of 50 collection devices per box and 10 boxes (500 devices) per shipping case (see Ordering Information below).

Pure•SAL™ Oral Specimen Collection System

Catalog Number: PRSAL-401

Qty: 50

4.0 mL Screw Cap Collection Vials

Catalog Number: MFGT-301

Qty: 100/500

Protein Stabilizing Reagent

Catalog Number: PSS-001

Qty: 20 mL

RNA Stabilizing Reagent

Catalog Number: RNAS-111

Qty: 20 mL

Optional Component

Tube Rack

Catalog Number: TRAC-001

Qty: 1

Final Note

Pure•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: 20160601

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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