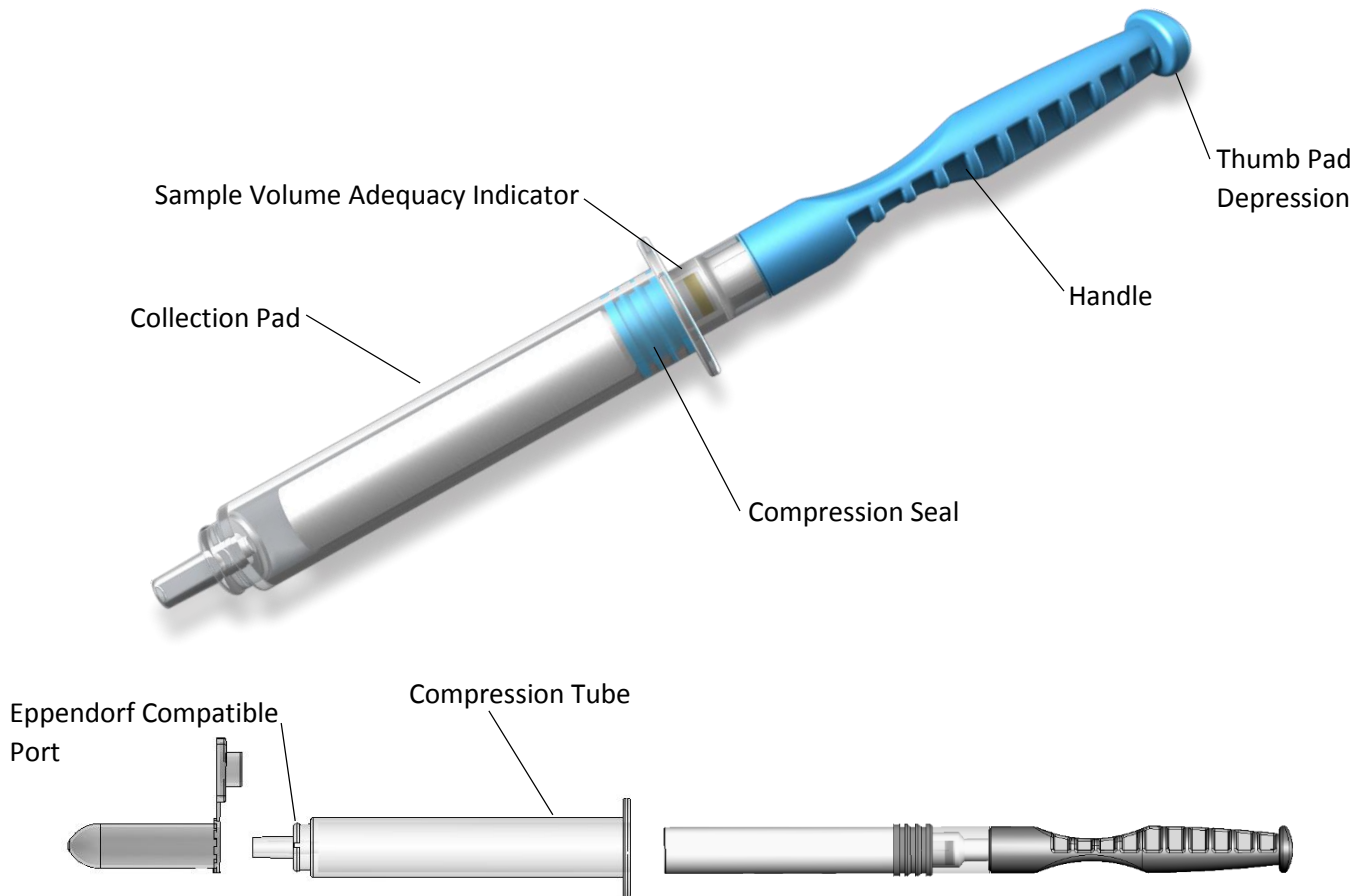


# SUPER•SAL™

## SALIVA COLLECTION DEVICE

Catalog Number: SSAL-601



### Intended Use

The Super•SAL™ Oral Fluid (Saliva) Collection Device is intended for the controlled, standardized collection and transportation of oral fluid (saliva) specimens for subsequent testing, analysis, or research applications. The devices do 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

Saliva is becoming an increasingly attractive bodily fluid for the easy, noninvasive and cost-effective replacement of traditional blood sampling and, as a result, a number of tools have been developed that allow for the simple collection of various components of saliva or “whole saliva”. A number of these have found specific and important applications within the expanding market for salivary diagnostics.(1.2)

Despite the availability of a number of available oral fluid collection devices, there are few that offer standardized saliva collection in a short time, with a built-in mechanism for sample sufficiency. Super•SAL™ incorporates both a novel Sample Volume Adequacy Indicator (SVAI) built into the device and provides a rapid method for large volume sampling of oral fluids/whole saliva for a variety of applications.

## Principles of the Device

The Super•SAL™ Oral Fluid/(Saliva) Collection Device is a proprietary, patented device intended for the standardized collection of whole saliva, from along the side of the tongue, adjacent to the gum line.

In order to collect an adequate specimen, subjects are requested to “pool” saliva in the mouth to facilitate faster collection times. The Super•SAL™ device features a cylindrical absorbent pad that facilitates rapid collection times. Saliva is released from the absorbent pad used to collect the specimen by compressing the pad through a narrow bore tube connected to a standard Eppendorf tube.

## Materials Provided

1. Super•SAL™ Saliva Collection Device.
2. Single Sample Transparent Compression Tube.
3. One Standard 2.0 mL Eppendorf Tube.

## Materials Required but not Provided

- (1) Timer
- (2) Preservative, if required.

## Instructions for Use

**PLEASE READ THE COMPLETE INSTRUCTIONS BEFORE PROCEEDING TO COLLECT ORAL FLUIDS / SALIVA USING THE SUPER•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.

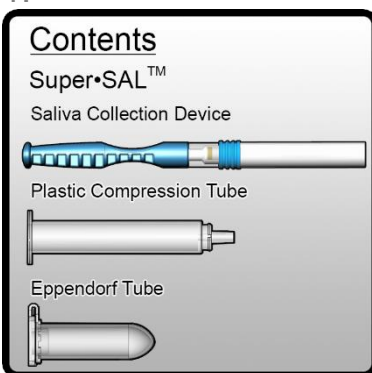
Rinse the mouth with water and discard. Please wait at least 5 minutes after this rinse to start the collection procedure (Figure 3 below).

During this time review the detailed instructions on the Super•SAL™ Saliva Collection Device insert below, particularly the illustrations showing the appearance of the Sample Volume Adequacy Indicator (SVAI) before and after sample collection (Figure 4 below).

## Step-by-Step Instructions

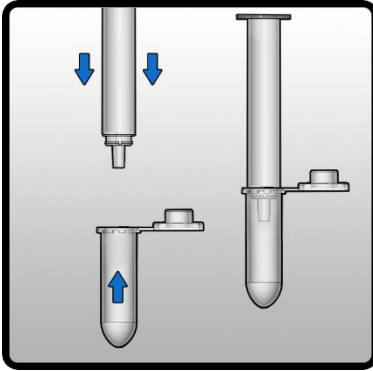
General Note: Ensure collection is continued until the Sample Volume Adequacy Indicator visually changes, confirming sample sufficiency [Figure 4 below].

1.



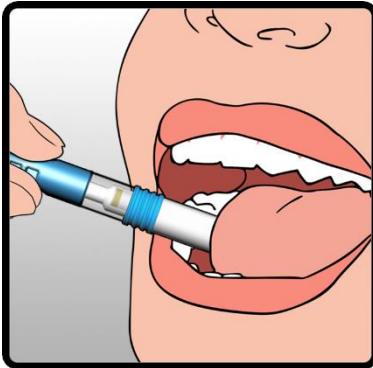
In preparation for oral fluid (saliva) collection place contents on a clean and dry surface away from any potential hazards which might contaminate components.

2.



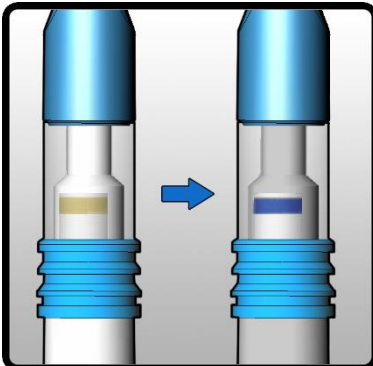
Attach the Eppendorf tube provided to the base of the Plastic Compression Tube firmly. In preparation for saliva collection pool saliva in the mouth. Sample collection may now begin.

3.



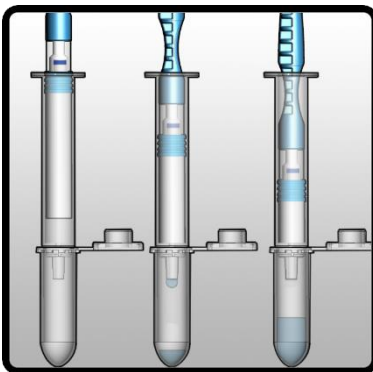
Place the white absorbent collection pad end of the Super•SAL™ device in the mouth, along the side of the tongue and collect until the appearance of the Sample Volume Adequacy Indicator [SVAI] changes from yellow to blue. (Illustration 4).

4.



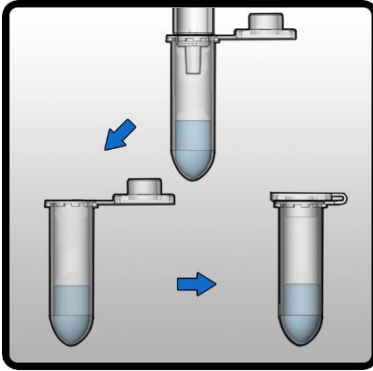
It is appropriate to remove the device from the mouth periodically in order to read the SVAI, but immediately return the collection device to the mouth and resume collection. The collection procedure should last approximately 1-3 minutes.

5.



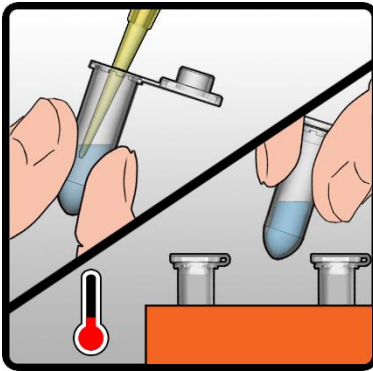
Place the white absorbent pad end into the Plastic Compression Tube holding the Super•SAL™ device in an upright and vertical position and firmly push the plunger downwards to transfer saliva from the absorbent pad into the Eppendorf Tube. Push and hold for 30 seconds.

6.



Gently remove the Eppendorf Tube from the end of the Plastic Compression Tube. Add preservative (not provided), if required, and close the lid on the tube tightly.

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>
SSAL-601	Super•SAL™ Saliva Collection Device
MFGT-301	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. 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 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 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 Super•SAL™ collection device by vortexing or centrifugation.
9. The absorbent material used to collect specimens contains no added salts, preservatives or other agents.
10. Testing of oral fluids (saliva) collected using the Super•SAL™ Oral Fluid Collection Device should be done according to validated protocols provided by test kit manufacturers. Oasis Diagnostics® Corporation provides no warranty as to the suitability of the Super•SAL™ Oral Fluid Collection Device, for any given application, other than the Intended Use described herein.
11. Super•SAL™ Oral Fluid Collection Devices 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 Super•SAL™ Oral Fluid Collection Device does not diagnose any disease.

## Ordering Information

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

### **Super•SAL™ Oral Fluid Collection Device**

Catalog Number: SSAL-601

Qty: 50

### **2.0 mL Eppendorf Tubes**

Catalog Number: EPDF-201

Qty: 50/500

### **Optional Component**

#### **Tube Rack**

Catalog Number TRAC-001

Qty: 1

## References

1. Slowey, P.D. “Commercial Saliva Collection Tools”, Journal of California Dentistry, 41 97-105 (2013)
2. Slowey P.D. and Punyadeera C. “Saliva as an Emerging Biofluid for Clinical Diagnosis and applications of MEMS/NEMS in Salivary Diagnostics.” Chapter 22 in Nanomaterials in Clinical Dentistry Edited by Subramani and Hartsfield. Elsevier, ISBN 978-1-4557-3127-5

## Final Note

Super•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



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