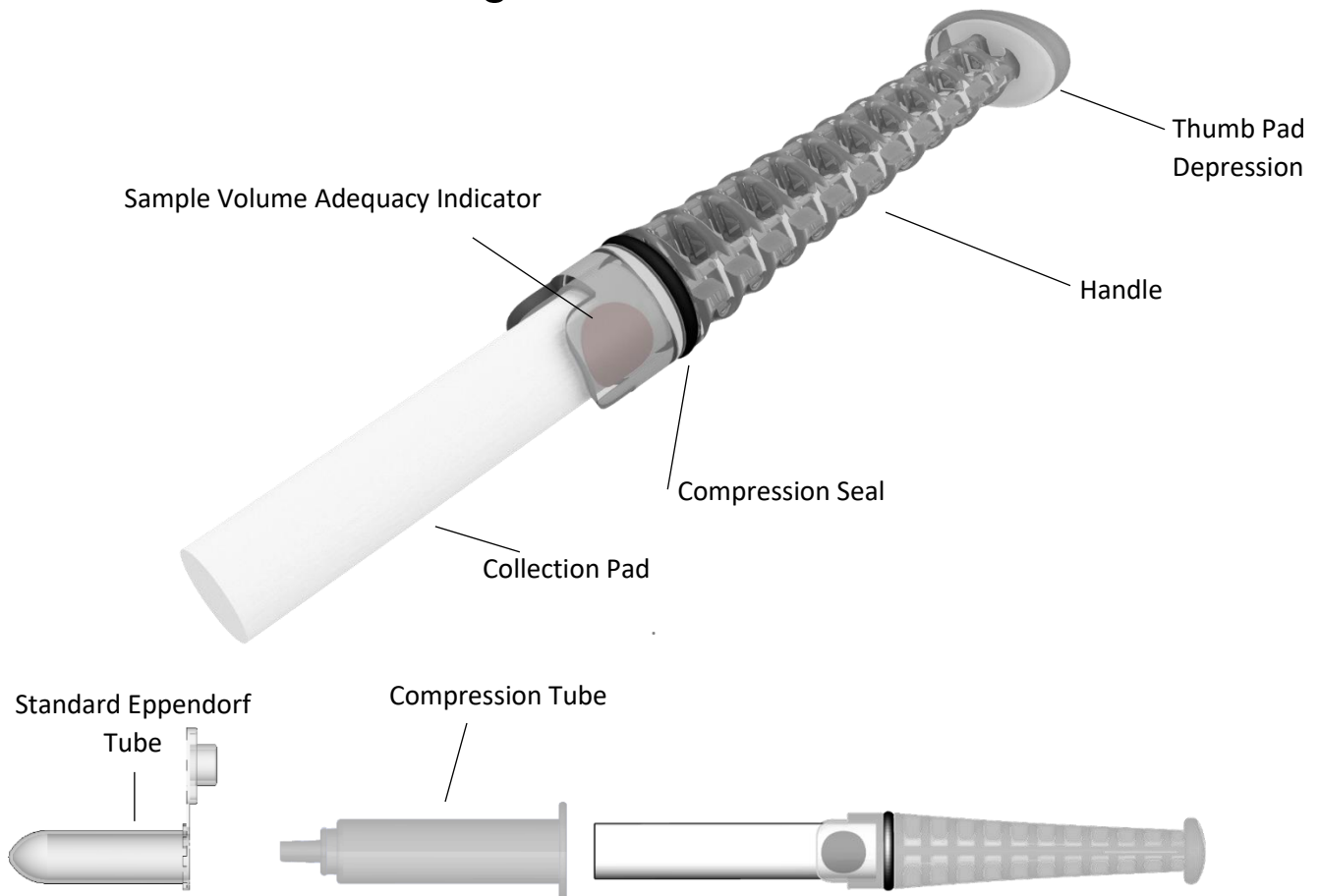


SUPER•SAL2™

UNIVERSAL SALIVA COLLECTION KIT

Catalog Number: SSAL-603



Intended Use

The Super•SAL2™ Universal Saliva Collection Kit is intended for the controlled, standardized collection and transportation of oral fluid (saliva) specimens for subsequent testing, analysis, or research applications. The kits 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 for traditional blood sampling. As a result, a number of tools have been developed that allow for the simple collection of various components of saliva or “whole saliva” equivalent to passive drool. Many of these have found specific and important applications within the expanding market for salivary diagnostics.^{1,2}

Despite the availability of a number of oral fluid collection devices, there are few that offer standardized saliva collection in a short time. Super•SAL2™ incorporates a built-in mechanism for sample sufficiency called a Sample Volume Adequacy Indicator (SVAI) and provides a rapid method for large volume sampling [~ 1mL] of oral fluids/whole saliva for a variety of applications.

Principles of the Device

The Super•SAL2™ Universal Saliva Collection Kit is a proprietary, patented system intended for the standardized collection of purified whole saliva.

In order to collect an adequate specimen, subjects are requested to pool saliva in the mouth to facilitate faster collection times. The Super•SAL2™ Collection Kit features a cylindrical absorbent pad that facilitates easy and rapid sample collection. Saliva is expressed from the absorbent pad through a Compression Tube into a standard Eppendorf tube.

Materials Provided

1. Super•SAL2™ Universal Saliva Collection Kit
2. Single Compression Tube
3. One Standard 2.0 mL Eppendorf Tube

Materials Recommended but Not Provided

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

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

Instructions for Use

PLEASE READ THE COMPLETE INSTRUCTIONS BEFORE PROCEEDING TO COLLECT PURIFIED WHOLE SALIVA USING THE SUPER•SAL2™ KIT. FAILURE TO FOLLOW THESE INSTRUCTIONS CAREFULLY COULD PRODUCE LESS THAN SATISFACTORY RESULTS.

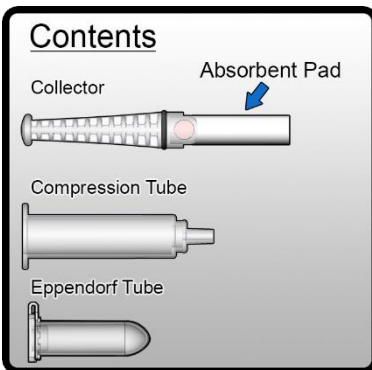
Do not eat, drink, smoke, or use oral hygiene products for at least 10 minutes before you start the collection process.

Prior to collection, review the detailed instructions on the Super•SAL2™ Universal Saliva Collection Kit 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

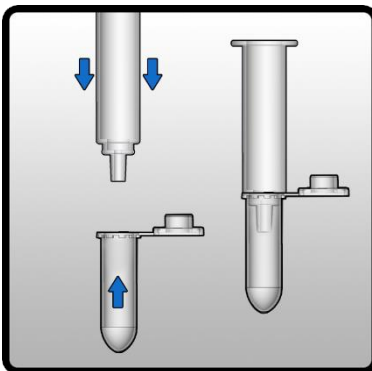
General Note: Ensure collection is continued until the Sample Volume Adequacy Indicator visually changes, confirming sample sufficiency [Figure 4 below].

1.



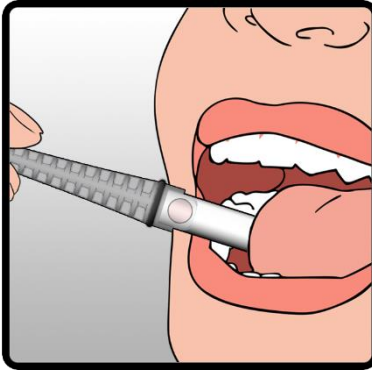
In preparation for purified whole saliva collection, place contents on a clean and dry surface. Video instructions are available on our website at: 4saliva.com/products/super-sal/

2.



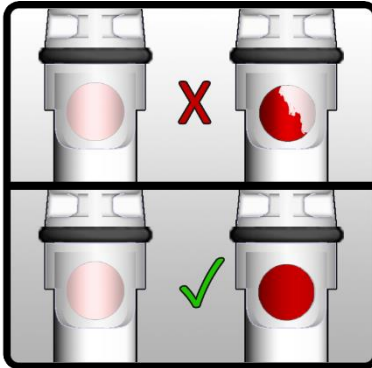
Firmly attach the Eppendorf tube provided to the base of the Compression Tube. In preparation for saliva collection, **pool saliva** in the mouth. Sample collection may now begin.

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.

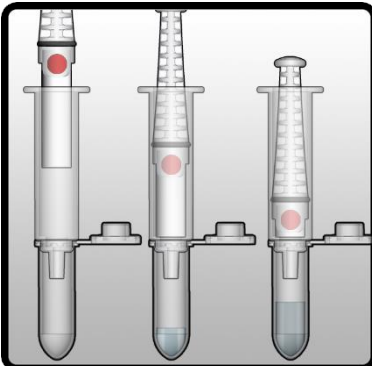


Collect until the appearance of the SVAI changes completely to red

OR

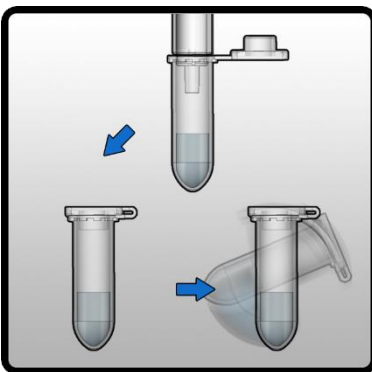
After having collected for 5 minutes (whichever occurs first).

5.



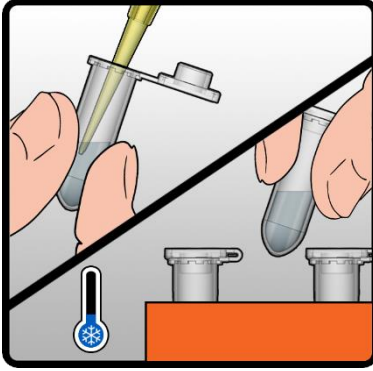
Place the white absorbent pad end into the Compression Tube holding the Collector in an upright and vertical position and firmly push the plunger downwards to transfer saliva from the absorbent pad into the Eppendorf Tube. Push and hold for 30 seconds.

6.



Gently remove the Eppendorf Tube from the end of the Compression Tube. It is appropriate to remove the Eppendorf Tube during expression if necessary due to foaming. 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-603	Super•SAL2™ Universal Saliva Collection Kit (with Compression Tube)
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 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 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 change within 15

minutes, express the sample to see if adequate volume 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, purified whole saliva may be removed from the Super•SAL2™ Collector by centrifugation.
9. The absorbent material used to collect specimens contains no added salts, preservatives or other agents.
10. Testing of purified whole saliva collected using the Super•SAL2™ Universal Saliva Collection Kit 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•SAL2™ Universal Saliva Collection Kit, for any given application, other than the Intended Use described herein.
11. Super•SAL2™ Universal Saliva Collection Kits are provided in clean 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•SAL2™ Universal Saliva Collection Kit does not diagnose any disease.

Ordering Information

Super•SAL2™ Universal Saliva Collection Kits are sold in units of 50 kits per box and 10 boxes (500 kits) per case (see Ordering Information below).

Super•SAL2™ Universal Saliva Collection Kit

Catalog Number: SSAL-603

Qty: 50

2.0 mL Eppendorf Tubes

Catalog Number: EPDF-201

Qty: 50/500

Optional Component

Tube Rack

Catalog Number TRAC-001

Qty: 1

Final Note

Super•SAL2™ Universal Saliva Collection Kits are available in different custom formats depending upon the required application. Please contact Oasis Diagnostics® Corporation for further details.

Manufactured by 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: 20200526

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:



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