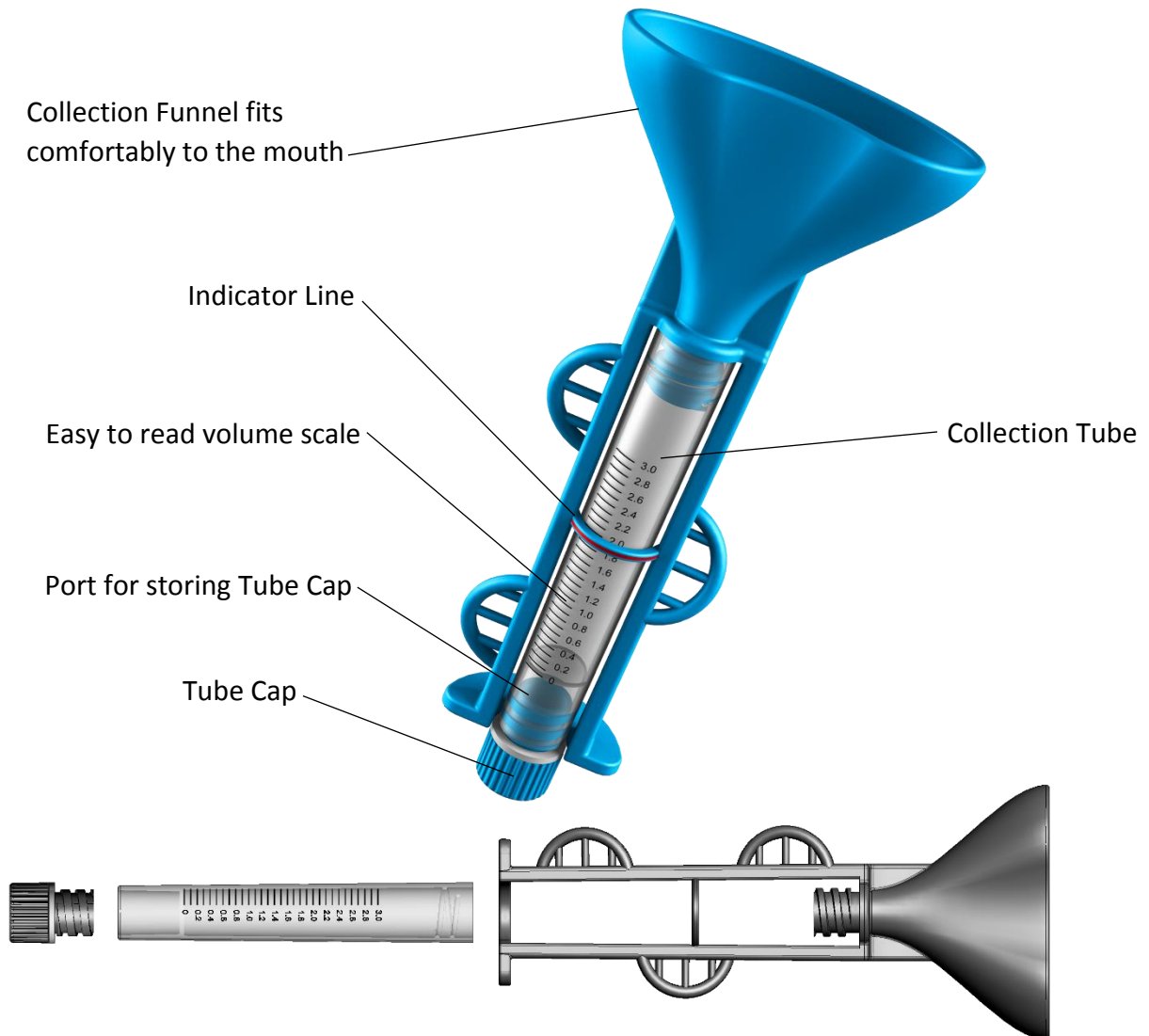


SimplIOFy™

Whole Saliva DNA Collection

Catalog Number SIMPL-301



Intended Use

The Oasis Diagnostics® Corporation SimplIOFy™ Whole Saliva DNA Collection Kit is intended for the collection and stabilization of whole saliva for subsequent extraction of DNA downstream testing. The SimplIOFy™ Whole Saliva DNA Collection Kit is For Research Use Only. Not for use in diagnostic procedures.

For research use only in the United States. The performance characteristics of this device have not been evaluated by the FDA.

Introduction

Use of oral samples for the isolation of DNA has become a very attractive alternative to isolation from blood or tissue for a number of compelling reasons: oral collection is fast, cost effective and noninvasive and may be performed by individuals with minimal training. In addition, no specialized equipment is required.

Human genomic DNA extracted from whole saliva collected using the proprietary SimplOFy™ Whole Saliva DNA Collection Kit can be used in a growing number of applications in the research and life sciences areas. Examples include the use of DNA in PCR-based molecular assays for the detection of disease or the determination of susceptibility to disease, applications in microarray technology, genotyping, personal genomics, genome wide association studies, next generation sequencing, and others. The ease of use of the SimplOFy™ kit makes it an ideal candidate for services requiring home collection and long term DNA stabilization at the point of collection.

Principles of the Device

The SimplOFy™ kit is a proprietary, patented system intended for the collection and stabilization of whole saliva DNA. To collect a specimen, subjects are requested to pool saliva in the mouth and 'expectorate' (spit) into the Collection Funnel until the sample reaches the brightly marked Indicator Line.

Once sample collection is complete, the Collection Tube is separated from the Collection Funnel by carefully rotating the Collection Tube until it is completely detached from the Collection Funnel. The Collection Funnel is then discarded and the Tube Cap is removed from the bottom of the Collection Tube and screwed tightly closed to the top of the Collection Tube.

The Tube Cap has dried-down stabilizing reagents inside, so the Collection Tube is continually inverted for at least 1 [one] minute, which results in adequate mixing of the stabilizing reagent with the saliva sample. The sample is now ready for transportation to a laboratory or storage for later testing.

Materials Provided

1. SimplOFy™ Whole Saliva DNA Collection Device

Materials Recommended but Not Provided

1. Disposable exam gloves
2. Container for proper disposal of used materials

Instructions for Use

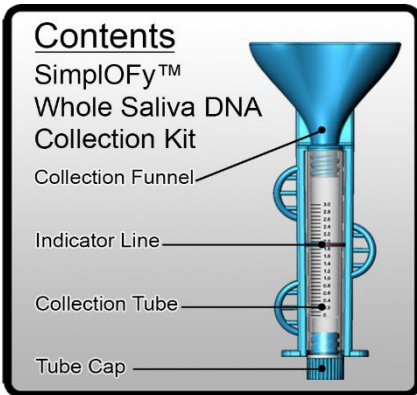
PLEASE READ THE COMPLETE INSTRUCTIONS BEFORE PROCEEDING TO COLLECT ORAL FLUIDS / SALIVA USING THE SIMPLOFY™ WHOLE SALIVA DNA COLLECTION KIT. FAILURE TO FOLLOW THESE INSTRUCTIONS CAREFULLY COULD PRODUCE LESS THAN SATISFACTORY RESULTS.

Do not eat, drink, smoke, or use oral hygiene products for at least 30 minutes before you start the collection process.

Prior to collection, review the detailed instructions for the SimplOFy™ Whole Saliva DNA Collection Kit below.

Step-by-Step Instructions

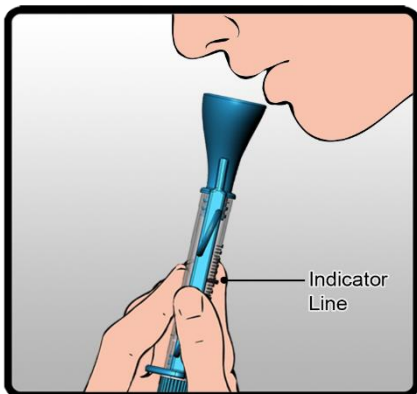
1.



Video instructions are available on our website at: 4saliva.com/products/simplify/

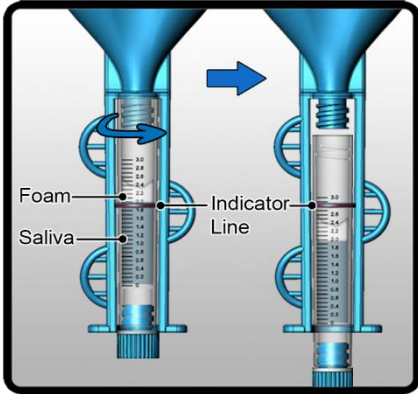
In preparation for oral fluid (saliva) collection, place contents on a clean and dry surface.

2.



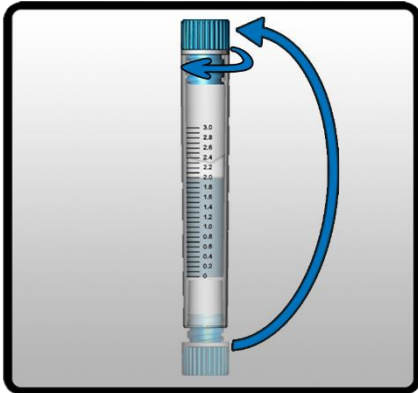
Pool saliva and spit into the opening of the Collection Funnel. Collect saliva until the sample level reaches the red Indicator Line (measure fluid level, not foam).

3.



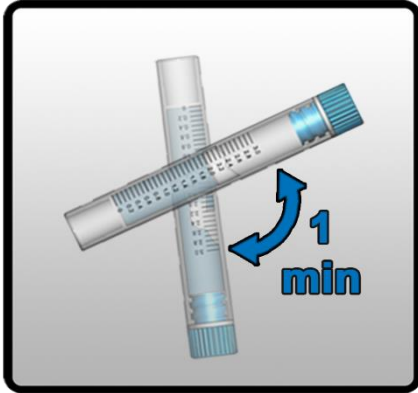
In an upright position, unscrew the Collection Funnel from the Collection Tube by rotating the Collection Tube in the direction shown until the Collection Tube is completely detached from the Collection Funnel.

4.



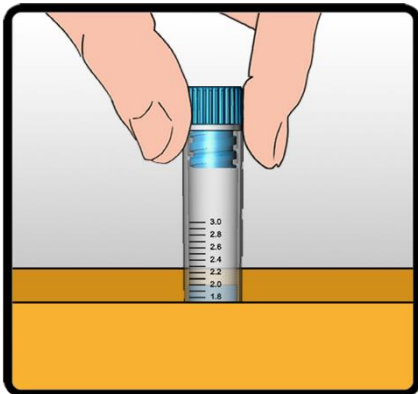
Carefully remove the Tube Cap from the bottom of the Collection Tube and screw the Tube Cap tightly closed on the top of the Collection Tube. Discard the Collection Funnel.

5.



Invert the vial for 1 minute to stabilize the sample.

6.



Sample is now ready for immediate testing or transportation to a laboratory using standard shipping methods for liquid samples.

NOTE: For extraction of DNA from saliva samples collected using the SimplOFy™ Whole Saliva DNA Collection Kit, the following kit options are recommended:

Product Description	Catalog Number
Oasis Mini•SAL™ Salivary DNA Isolation Kit [30 Preparations]	DNAX-504-30
Oasis Midi•SAL™ Salivary DNA Isolation Kit [30 Preparations]	DNAX-505-30

KIT COMPONENTS

<u>Catalog Number</u>	<u>Item</u>
SIMPL-301	SIMPLOFY™ WHOLE SALIVA DNA COLLECTION KIT

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 appropriate biohazardous waste containers.
4. Do not use kits beyond the expiration date printed on the pouch.
5. Prior to use, record patient / subject information on the Collection Tube.
6. Collect until the Indicator Line provides a visual indication that the required volume has been collected. Make sure to measure fluid level, not foam.
7. SimplOFy™ Whole Saliva DNA Collection Kits are provided in clean, non-sterile form but may be provided in sterile form upon request.
8. Store at room temperature (15-30°C) until the expiration date written on the exterior of the pouch.

9. The SimplOFy™ Whole Saliva DNA Collection Kit does not diagnose any disease.

Ordering Information

SimplOFy™ Whole Saliva DNA Collection Kits are sold in units of 25 collection devices per box and 10 boxes (250 kits) per shipping box (see Ordering Information below).

SimplOFy™ Whole Saliva DNA Collection Kit

Catalog Number: SIMPL-301

Quantity: 25/250

Final Note

SimplOFy™ Whole Saliva DNA Collection Kits 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 Pending.

Rev: 05102017

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