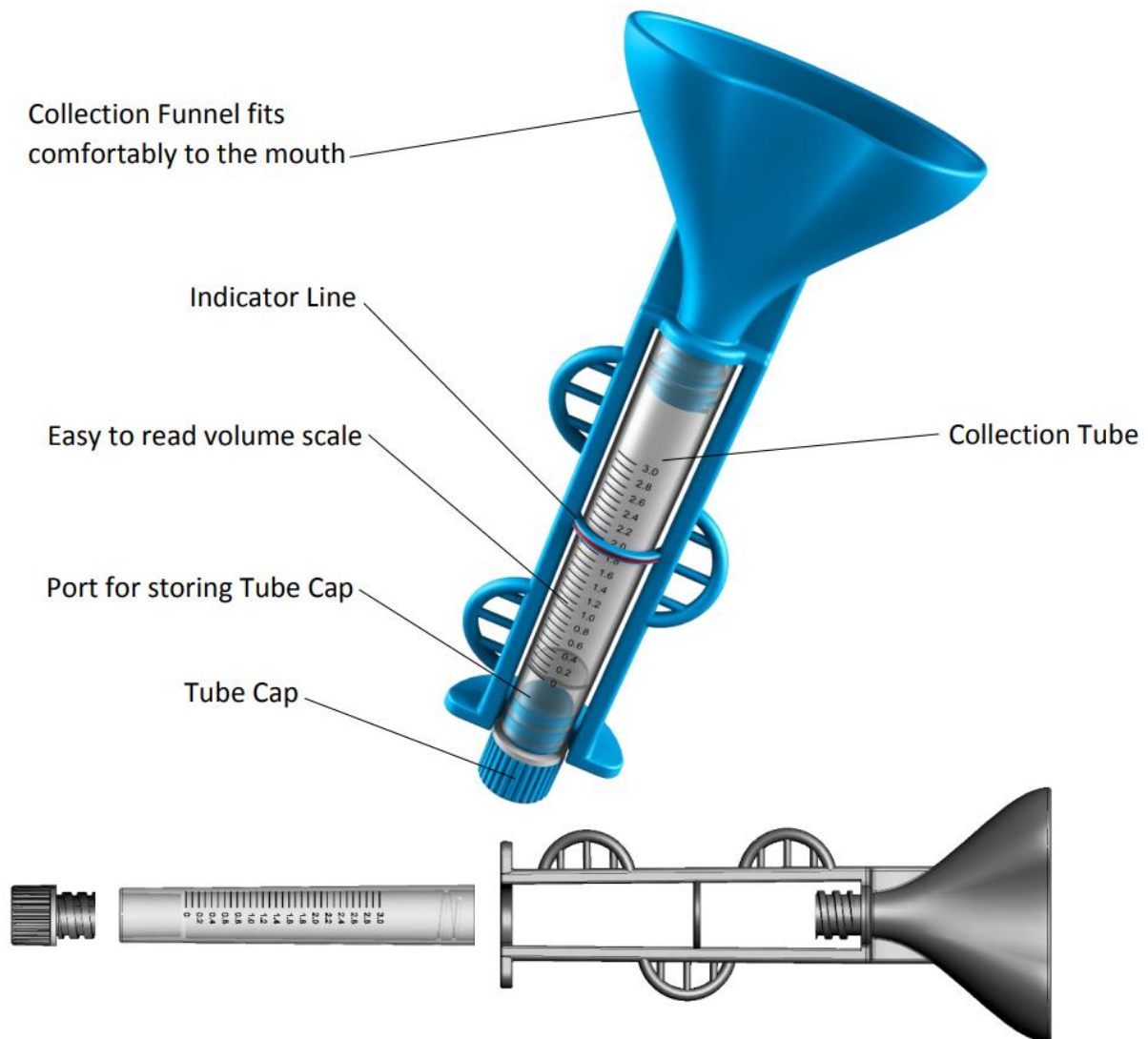


SimplOFy™ Saliva DNA Collection Kit

Catalogue number: SALV-003

Note: For Research Use Only [RUO]. Not for Use in Diagnostic Procedures.



Intended use

- The SimplOFy™ Saliva DNA Collection and Stabilisation Kit is intended for the collection and stabilisation of whole saliva (oral fluid) for subsequent extraction of DNA for downstream testing. Dried down stabilising buffer optimised for DNA is embedded in the blue tube cap. The kits do not provide any diagnosis of disease.
- Ideal for the easy collection and stabilisation of salivary DNA.

Principles of the device

- The SimplOFy™ kit is a proprietary, patented system intended for the collection and stabilisation 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 indicating that 2.0 mL of saliva has been obtained.
- 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 blue Tube Cap contains embedded dried-down stabilising reagents allowing for a quick and efficient stabilisation process optimised for DNA. After sample collection, the Collection Tube is continually inverted for at least 1 minute, which results in adequate mixing of the stabilising reagent with the saliva sample. The sample is now ready for transportation to a laboratory or storage for later testing.

Materials provided

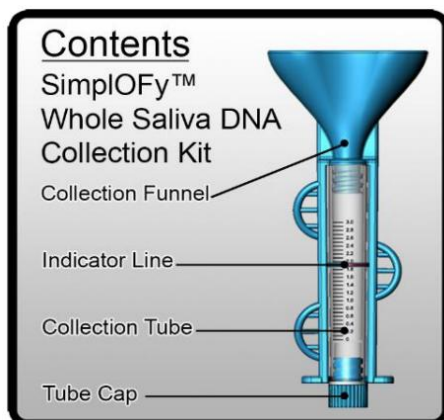
- SimplOFy™ Saliva DNA Collection and Stabilization Kit.

Instructions for use

- PLEASE READ THE COMPLETE INSTRUCTIONS BEFORE PROCEEDING TO COLLECT THE SAMPLE. FAILURE TO FOLLOW THESE INSTRUCTIONS CAREFULLY COULD PRODUCE SUB-OPTIMAL RESULTS.
- Prior to collection, review the detailed instructions below.
- Do not eat, drink, smoke, or use oral hygiene products for at least 10 minutes before commencing the collection process.

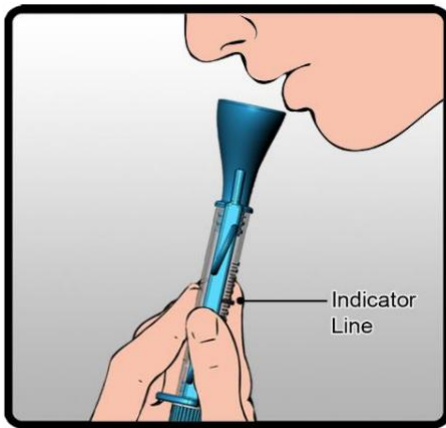
Step by step instructions

1. Ensure collection is continued until the Sample Volume Adequacy Indicator visually changes, confirming sample sufficiency.



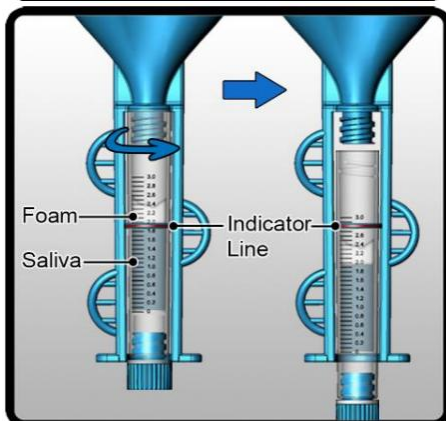
Open the package and place the contents on a clean and dry surface.

2.



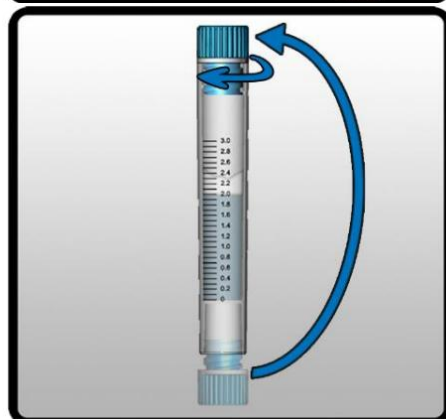
Pool saliva and spit into the opening of the Collection Funnel. Collect saliva until the sample level reaches the red Indicator Line (measure fluid level, not foam). This indicates that 2.0 mL has been collected.

3.



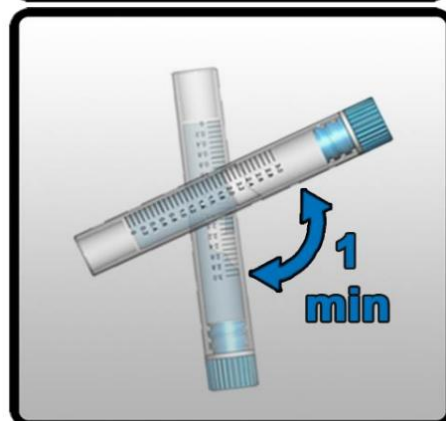
In an upright position, unscrew the Collection Funnel from the Collection Tube by rotating the Collection Tube in the direction shown until the Collection Tube is completely detached from the Collection Funnel.

4.



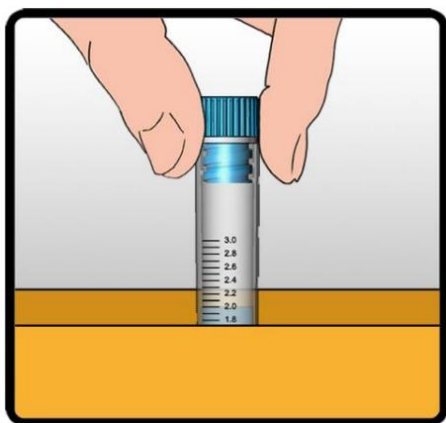
Carefully remove the Tube Cap from the bottom of the Collection Tube and screw the Tube Cap tightly closed on the top of the Collection Tube. Discard the Collection Funnel.

5.



Invert the vial for 1 minute to stabilise the sample.

6.



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

Precautions and notes

- DO NOT DRINK WHILE COLLECTION IS IN PROGRESS.
- DO NOT REUSE OR SUBSTITUTE KIT COMPONENTS.
- Kits are for single use only. Used collectors and samples should be disposed of in accordance with local requirements for clinical waste.
- Do not use kits beyond the expiration date printed on the pouch.
- Prior to use, record subject information on the Collection Tube.
- Collect until the Indicator Line provides a visual indication that the required volume has been collected. Make sure to measure fluid level, not foam.
- Salvivo Ltd. and Oasis Diagnostics® Corporation provide no warranty as to the suitability of the SimplOFy™ Saliva DNA Collection Kit, for any given application, other than the Intended Use described herein.
- SimplOFy™ Saliva DNA Collection Kits are rigorously tested for compliance with United States Pharmacopeia (USP) for non-sterile products but may be provided in sterile form upon request.
- Store at room temperature (15-30°C) until the expiration date written on the exterior of the pouch.
- The SimplOFy™ Saliva DNA Collection Kit does not diagnose any disease.

Ordering information

- SimplOFy™ Saliva DNA Collection Kits are sold in units of 25 collection kits per box and 10 boxes (250 kits) per shipping box. Please contact Salvivo Ltd. regarding your requirements.

Final note

- Manufactured by Oasis Diagnostics® Corporation in the United States.
- This device is protected by US and EU Patents pending.

Technical support

- For Technical Support please contact Salvivo Ltd. via the contact details below.



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