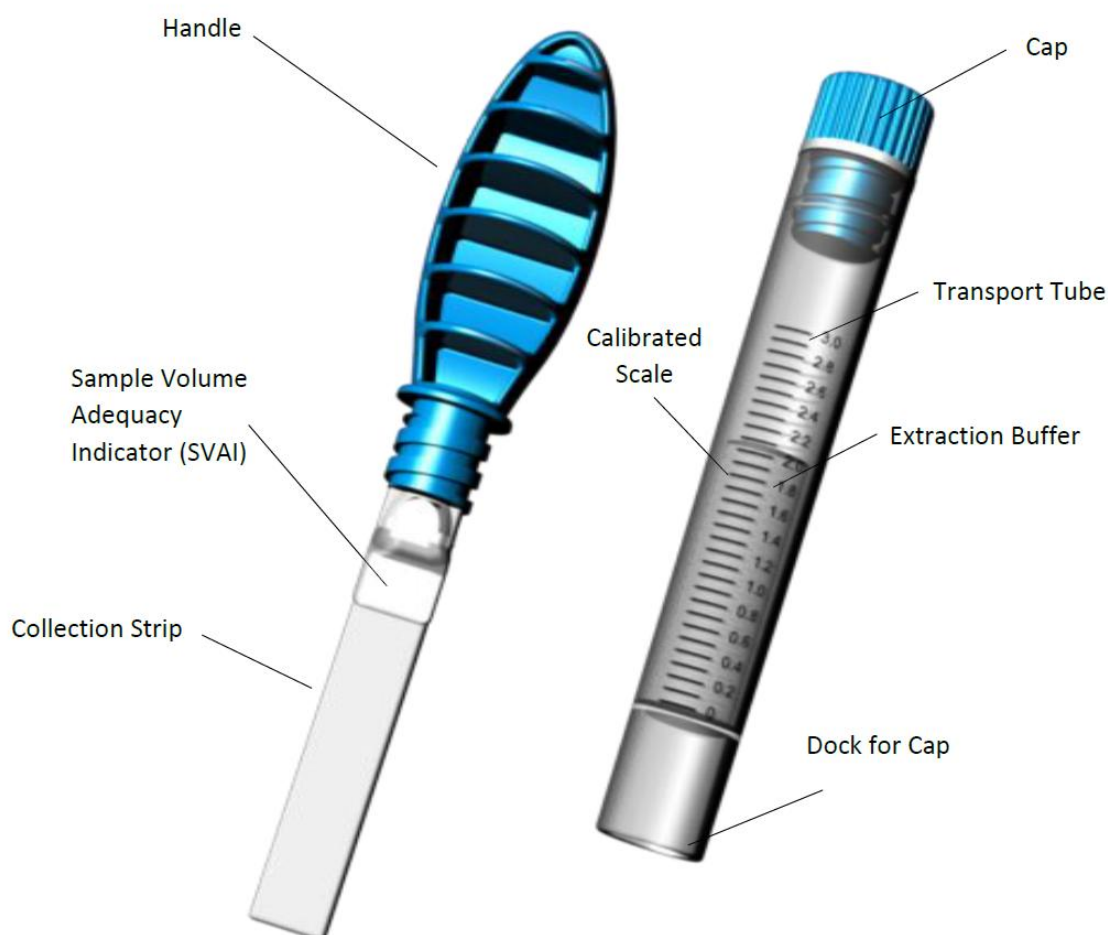


Accu-SAL™ Saliva Collection Kit

Catalogue number: SALV-006

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



Intended use

- Accu-SAL™ is a saliva (oral fluid) collection system intended for the controlled and standardized collection and transportation of oral fluid specimens for the purpose of subsequent testing for various drug molecules, metabolites, steroid hormones, and other molecules. The device does not provide any diagnosis of disease.
- Collection time 1-2 minutes.
- Sample Volume Adequacy Indicator and calibrated scale.
- Ideal for the collection of drug molecules including therapeutics and drugs of abuse.

Principles of the device

- The Accu-SAL™ Saliva Collection Kit is a proprietary patented device for the standardized collection of whole saliva (oral fluid) from the side of the tongue in the mouth. In order to collect an adequate specimen, it is recommended that subjects pool saliva in the mouth just prior to sample collection to facilitate faster collection times.
- The Accu-SAL™ Saliva Collection Kit features a Collection Strip comprising an Absorbent Pad material, which is placed in the pool of saliva to the side of and under the tongue and adjacent to the lingual surfaces (inside surfaces) of the lower teeth to collect the sample. After 1-2 minutes, the Sample Volume Adequacy Indicator (SVAI) changes appearance signifying that sufficient saliva has been collected for subsequent analysis.
- The Collection Strip is then transferred to the transport tube for transportation to a laboratory. Upon receipt at the laboratory the sample may be removed by vortexing and/or centrifugation if it has received insufficient inversion during transit and is then ready for analysis by various methods. It is not always possible to obtain an adequate quantity of saliva, especially in cases where the subject/donor is suffering from dry mouth. In these instances, the quantity of saliva collected using the Accu-SAL™ Saliva Collection Kit can be calculated from the amount of liquid displaced in the Accu-SAL™ Buffer Tube when the Collection Strip is introduced into the Transport Buffer (see below).

Materials provided

- Accu•SAL™ Collection Strip attached to ergonomically designed handle.
- Graduated Transport Tube containing Transport Buffer (2.0 mL).

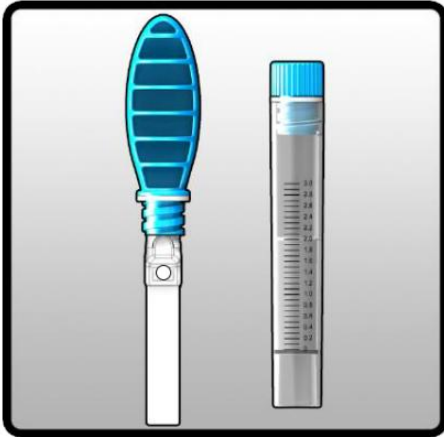
Instructions for use

- 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, particularly the illustrations showing the appearance of the SVAI before and after sample collection.
- Do not eat, drink, smoke, or use oral hygiene products for at least 10 minutes before commencing the collection process.

Step by step instructions

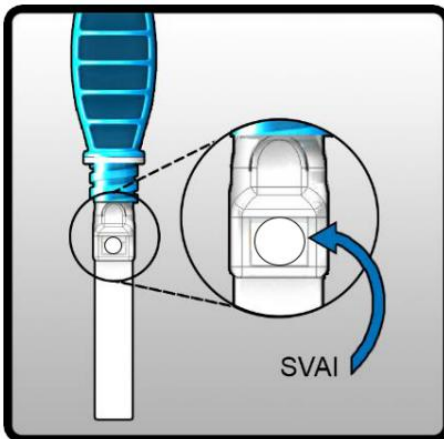
- Ensure collection is continued until the Sample Volume Adequacy Indicator (SVAI) visually changes, confirming sample sufficiency.

1.



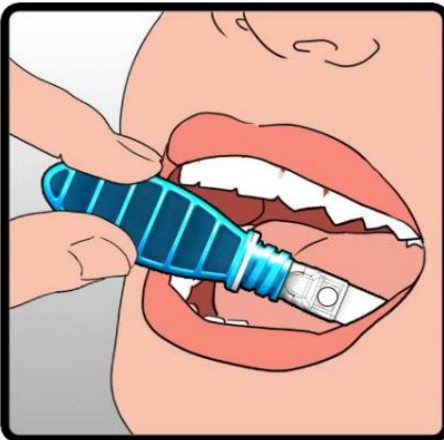
Open the package containing the Accu-SAL™ Saliva (Oral Fluid) Collection Kit. Remove the Collection Strip by the Handle

2.



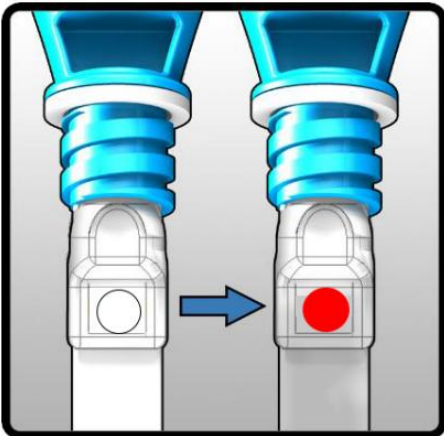
View the SVAI just beneath the handle, with the front of the handle facing you, by looking directly at the SVAI with the strip held at a slight angle away from you.

3.



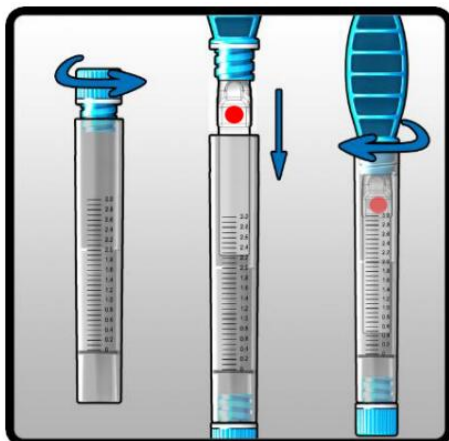
While holding the Handle, place the Collection Strip in the mouth. Allow the Collection Strip to absorb saliva that has been pooled. Continue to pool and absorb saliva while moving the Collection Strip further into the mouth with the goal of saturating the entire pad.

4.



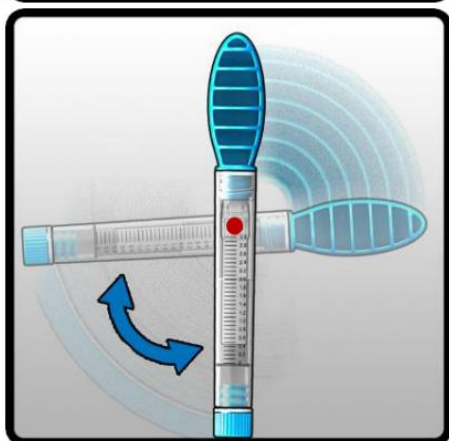
Remove the Collection Strip from the mouth every 15-20 seconds and continue collecting until the SVAI changes from white to red (see left). Sample collection is now complete.

5.



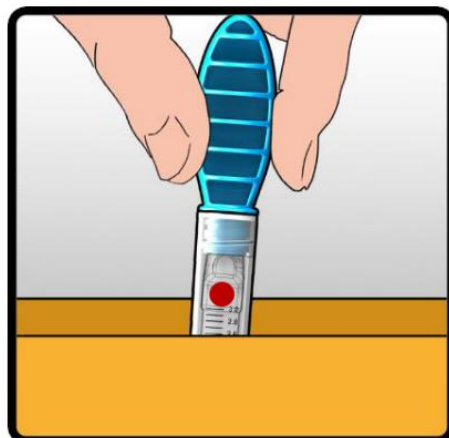
Remove the cap from the Transport Tube containing the Extraction Buffer and push the cap into the dock located in the bottom of the Transport Tube. Place the saturated pad connected to the Handle into the Transport Tube containing the Extraction Buffer and screw the cap tightly onto the Transport Tube.

6.



Invert Transport Tube 5-10 times.
(Note: If the sample is to be processed immediately, invert the Transport Tube 20-40 times).

7.



Process the collected sample immediately or store for future analysis, according to the requirements of the analyte(s) to be tested. Alternatively, place the sealed Transport Tube containing the Collection Strip and Extraction Buffer into an appropriate shipping container for transportation to a laboratory using standard shipping methods for liquid samples.

Sample analysis instructions

- Recovery of analytes: Recovery of analytes from the Accu-SAL™ Saliva Collection Kit will depend upon the structure of the analyte being tested. Some analytes bind tightly to cellular material and other components of saliva are trapped by the collection matrix. It is strongly recommended that spiked recovery experiments be performed for each analyte of interest using appropriate protocols. Expect that recovery of sample from the Collection Strip will depend heavily upon time of exposure to the Extraction Buffer and the number of mixing inversions. Transporting samples by mail or long courier times is usually sufficient to ensure maximum extraction / recovery.

- If the SVAI has changed from white to red during the sample collection process, the quantity of saliva held within the absorbent Collection Strip is 0.7 mL. This is then placed into the Transport Tube which contains 2.1 mL of Extraction Buffer. Therefore, there is a dilution factor of the saliva sample of 1:4.

Note: Absolute recovery of saliva from the Accu-SAL™ Saliva Collection Strip will depend upon the method used. Mixing of the sample by inversion after collection alone may not result in complete extraction of the target analyte. Vortexing the Transport Tube with the Collection Strip inside for 15 seconds typically results in complete extraction; however, the vortexing action can also remove fine particulates from the pad and these particulates may present a problem in some instances when using automated pipetting equipment or other pipetting methods that use low bore diameter tips that can clog. In these cases, extraction methodology will need to be validated by the laboratory depending upon the final usage. Centrifugation of the tube containing the Collection Strip and Transport Buffer will pellet the fine particulates and allow unhindered pipetting at the top of the solution column.

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 Eppendorf Tube.
- During sample collection, ensure that the subject does not chew or suck on the absorbent collection strip.
- Collect until the SVAI provides a visual indication that the required volume has been collected. Typical collection time is 1–2 minutes. If the requisite sample has failed to collect within 10 minutes discard the device and begin a further collection with a fresh device. 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.
- The absorbent collection strip used to collect specimens contains no added salts, preservatives or other agents.
- Analysis of whole saliva collected using the Accu-SAL™ Saliva (oral fluid) Collection Kit should be done according to validated protocols according to assay requirements.
- Salvivo Ltd. and Oasis Diagnostics® Corporation provide no warranty as to the suitability of the Accu-SAL™ Saliva (oral fluid) Collection Kit, for any given application, other than the Intended Use described herein.
- Accu-SAL™ Oral Fluid 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 Accu-SAL™ Oral Fluid Collection Kit does not diagnose any disease.

Ordering information

- Accu-SAL™ Saliva (Oral Fluid) Collection Kits are sold in units of 50 collection kits per box and 10 boxes (500 Kits) per case. 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 including US Patent Numbers 7618591, 7927548, 8273305 and others.

Technical support

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



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