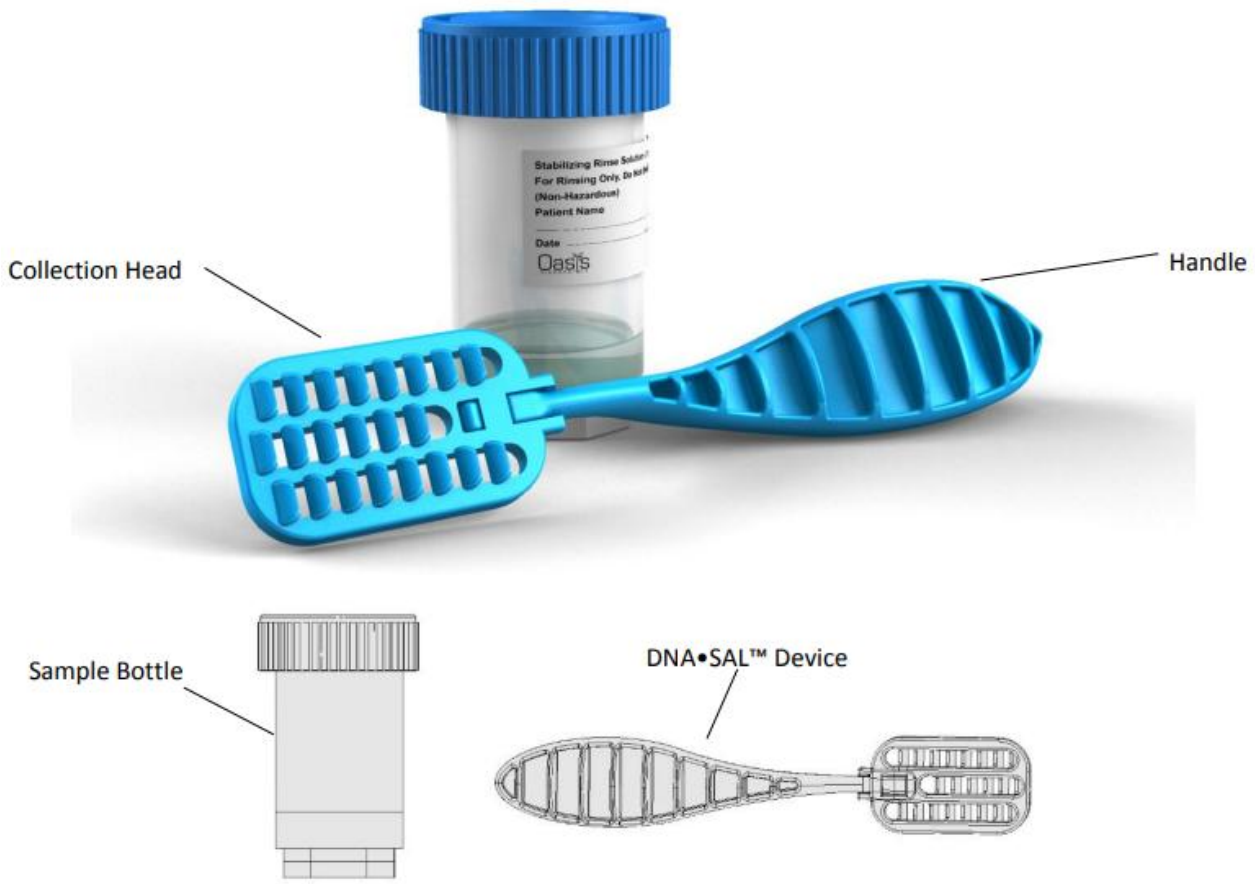
DNA-SAL™ Salivary DNA Collection Kit

Catalogue number: SALV-008

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



Intended use

- The DNA-SAL™ Salivary DNA Collection Kit is intended for the collection of saliva enriched with epithelial cells for subsequent extraction of DNA from oral specimens. The DNA-SAL™ Salivary DNA Collection Kit is for research or investigational use only. The kits do not provide any diagnosis of disease.
- Collection time in less than 1 minute, with high DNA yield.
- Suitable for multiple downstream technologies (PCR, sequencing, genotyping, and more).
- Ideal for the collection of salivary DNA/RNA.

Principles of the device

- The DNA-SAL™ Salivary DNA Collection Kit is a proprietary patented device intended for the collection of saliva rich in DNA by abrasion of cells on the inside of the cheek, using a series of serrated edges on the platform of the Collection Device.
- Within a few seconds, a combination of cells accumulates in voids created on the surface of the DNA-SAL™ tool. A significant number of additional cells are dislodged and freely available in the saliva in the mouth.
- After raking the buccal mucosa (inside of the cheek) for 30 seconds, the DNA-SAL™ Salivary DNA Collection Device is removed from the mouth, then a small quantity of a pre-dispensed Stabilising Rinse Solution is placed in the mouth, by drinking from a Collection Tube. This solution is then “swished” around the area where cells have been abraded for a few seconds, then expectorated (“spitted back”) into the same Collection Tube.
- The handle of the DNA-SAL™ Salivary DNA Collection Device is detached from the Collection Head, and the detached head is then dropped carefully into the Collection Tube containing the mixture of Stabilising Rinse Solution and saliva.
- The Collection Tube and specimen can then ne immediately processed to extract DNA for downstream applications or shipped to a remote laboratory for isolation of DNA.

Materials provided

- DNA-SAL™ Salivary DNA Collection Device.
- Collection Tube (Containing Stabilising Rinse Solution).

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.
- Pool saliva in the mouth and ensure the insides of the cheeks are moist with saliva.
- Do not eat, drink, smoke, or use oral hygiene products for at least 10 minutes before commencing the collection process.

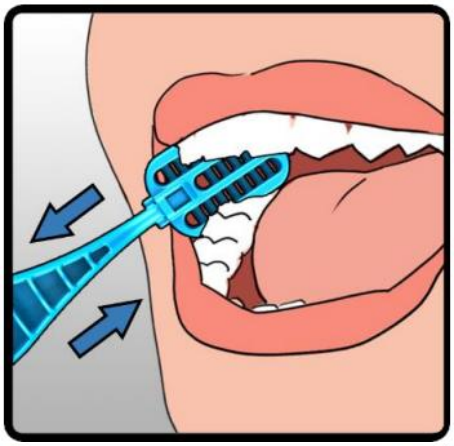
Step by step instructions

- Ensure collection is continued until the Sample Volume Adequacy Indicator visually changes, confirming sample sufficiency (Figure 4 below).

1.

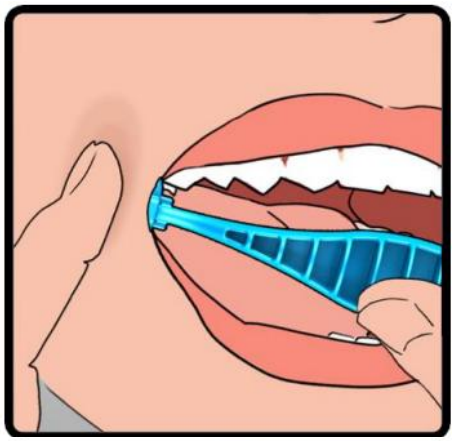
Open the Collection Tube containing the Stabilising Rinse Solution provided and set down the Tube and Cap on a flat surface.

2.



Take the DNA-SAL™ Salivary DNA Collection Device and place in the mouth with the Collection Teeth parallel to the inside of the cheek, towards the LOWER part of the inside of the cheek next to where the lower teeth are located.

3.



Place a finger on the **outside** of the cheek (to provide resistance) while collecting the sample and rake the Collection Teeth with **gentle** pressure along the inside of the cheek for 30 seconds. Cellular material may be visible in the Collection Area of the DNA-SAL™ Salivary DNA Collection Device but the appearance of this is not a requirement as a significant quantity of additional cells will remain in free-flowing saliva in the mouth and will be collected by rinsing.

4.

Remove the device from the mouth and hold in one hand. Using the other hand, pour the contents of the Collection Tube (2 mL of a safe Stabilising Rinse Solution) into the mouth and swish around for 15 seconds. **DO NOT SWALLOW**. After 15 seconds, expectorate the mixture of Stabilising Rinse Solution and saliva back into the Collection Tube.

5.

Insert the DNA-SAL™ Salivary DNA Collection Device with the Collection Area pointing downwards into the Collection Tube and **snap off** the head of the device in the neck of the Collection Tube by bending backwards until the Collection Head of the DNA-SAL™ Device drops off and into the Collection Tube.

6.

Discard the Device Handle and screw the Cap of the Collection Tube down tightly to secure the Sample.

7.

Shake the Collection Tube (now containing a mixture of Stabilising Rinse Solution, saliva and cells) vigorously for 15 seconds to mix the Stabilising Rinse Solution and Sample.

8.

The Sample is now ready for immediate processing or for transportation to a laboratory.

- The utility of isolated DNA for downstream applications is dependent upon extraction of high-quality DNA in sufficient quantity for analysis and also in obtaining a stable sample that has been protected from degradation by the addition of stabilising agents. As part of the validation process, DNA harvested using the DNA-SAL™ Salivary DNA Collection Kit was evaluated for three important performance characteristics: quantity recovered, quality [purity] and sample stability in a series of three experiments carried out by independent investigators.
- **Quantity of Isolated DNA**. The DNA-SAL™ Salivary DNA Collection Kit provides a mixture of saliva, epithelial cells and Stabilising Rinse Solution that may be readily extracted to provide high yields of purified DNA. The total volume of solution available for extraction varies from subject to subject, but typically the DNA-SAL™ Salivary DNA Collection Kit provides a minimum volume of 3 mL of solution for subsequent purification. NOTE: It is customary to quantify the amount of DNA isolated post-extraction in terms of the number of micrograms per milliliter (µg/mL) of DNA. From this value DNA isolated [µg] can readily be calculated. The following results were observed from a total of n=8 samples: Average concentration of DNA obtained based on a specimen size of 500µl using an ethanol precipitation DNA isolation protocol = 123.6 µg/mL. Average concentration of DNA obtained based on a specimen size of 400 µl, using a DNA binding (spin column) DNA isolation protocol = 62.4 µg/mL. Using an automated robotic system (Maxwell 16 + Promega Wizard) for sample manipulation an average value of 27.3 µg/mL was observed.
- **DNA Quality** (Purity). DNA quality was assessed by measuring the absorbance values at three wavelengths: 230 nm, 260 nm and 280 nm and calculation of the appropriate A260 / A280 and A260 / A230 ratios, according to standard procedures. Pure DNA is reported to have an A260 / A280 ratio of 1.7- 2.0 and an A260 / A230 ratio >1.5. An independent evaluation of DNA purity following isolation of DNA from samples collected using the DNA-SAL™ Salivary DNA Collection Kit was assessed using n=8 samples collected and stored in the Stabilising Rinse Solution provided with each DNA-SAL™ Salivary DNA Collection Kit. Assessment of purity was carried out following DNA isolation using a DNA binding (spin column) extraction method followed by adaptation to an automated robotic system (QiaCube, Qiagen, Gemany) for sample handling and manipulation. Average A260 / A280 observed (n=8) = 1.83. Average A260 / A230 observed (n=8) = 2.67. NOTE: Quality of isolated DNA is highly dependent upon the method of isolation used (ethanol precipitation versus DNA binding methods versus 96 well microplate extraction), as well as from kit manufacturer to kit manufacturer. It is therefore recommended that a method optimized for the isolation of DNA from saliva and/or buccal cells is used.
- **Stability.** In order to assess the stability of salivary samples collected using the DNA-SAL™ Salivary DNA Collection Kit, n=3 samples were collected according to the instructions provided. After rinsing with the Stabilising Rinse Solution, the solution was expectorated ("spitted back") into the Collection Tube provided and stored at ambient temperature [15-30°C]. Samples were aliquoted and tested immediately [day 0] and subsequently at days 1, 3, 5, 10, 20 and 30, and checked for DNA degradation using agarose gels/gel electrophoresis. All samples showed no degradation up until and including Day 30 indicating that the Stabilising Rinse Solution confers stability of a minimum of 30 days on DNA.

- **Application to PCR Testing.** In order to test the suitability of the isolated DNA for down-stream testing, DNA from saliva samples collected using the DNA-SAL™ Salivary DNA Collection Kit was run in parallel to DNA extracted from whole blood, using the Gen Xtract isolation kit from ViennaLab Diagnostics [Vienna, Austria], in two reverse transcriptase PCR StripAssay® kits for alpha-Thalassemia and hemochromatosis. In each case the protocol used was that provided by the manufacturer. The StripAssay® test provides visual results and in these experiments the observed results for each assay were identical for blood and saliva confirming that a combination of sample collection using the DNA-SAL™ Salivary DNA Collection Kit and DNA isolation using established DNA extraction kits provides an acceptable method of sample purification as an initial step prior to PCR testing.

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.
- During sample collection, ensure that the subject does not chew or suck on the collection device.
- Perform the raking action with the Collection Head gently to avoid traumatising the buccal mucosa.
- Ensure that the Collection Tube containing the Stabilising Rinse Solution is placed on a flat surface.
- When closing the Collection Tube, please ensure that the lid is tightly fastened.
- Avoid introducing any foreign objects into the Collection Tube after opening.
- Stabilisation and analysis of samples collected using the DNA-SAL™ Salivary DNA 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 DNA-SAL™ Salivary DNA Collection Kit, for any given application, other than the Intended Use described herein.
- DNA-SAL™ Salivary 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 DNA-SAL™ Salivary DNA Collection Kit does not diagnose any disease.

Ordering information

- DNA-SAL™ Salivary DNA Collection Kits are sold in units of 50 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 US Patent D627882 and foreign and domestic patent and trademark rights.

Technical support

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

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