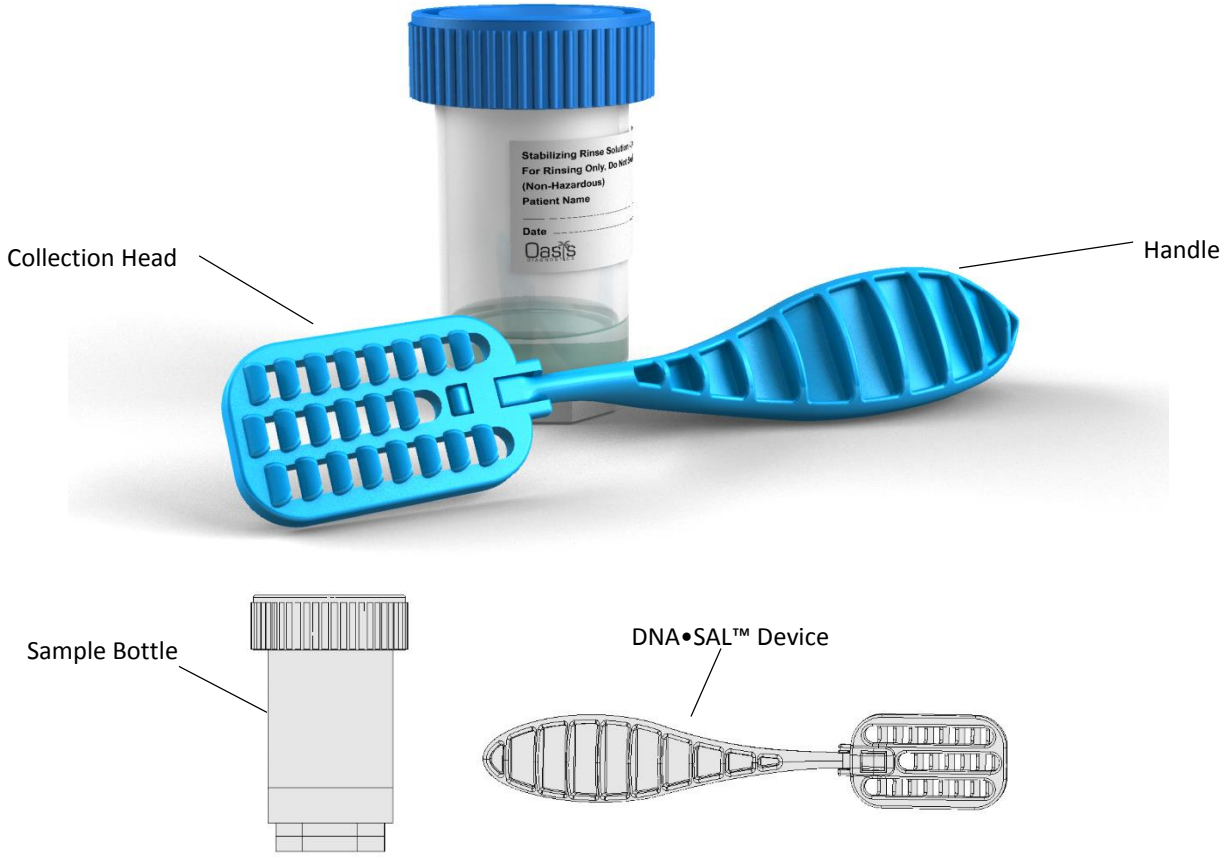
DNA•SAL™

SALIVARY DNA COLLECTION DEVICE

Catalog Number: DNAS-102



Intended Use

The Oasis Diagnostics® Corporation DNA•SAL™ Salivary DNA Collection Device 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 Device is For Research or Investigational 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 a combination of epithelial cells and white blood cells collected using the proprietary DNA•SAL™ Salivary DNA Collection Device can be used in a growing number of applications in 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 DNA•SAL™ Salivary DNA Collection Device can be used for this purpose.

Principles of the Device

The DNA•SAL™ Salivary DNA Collection Device collects and harvests 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 accumulate 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 for 30 seconds, the DNA•SAL™ Salivary DNA Collection Device is removed from the mouth, then a small quantity of a pre-dispensed Stabilizing Rinse Solution is placed in the mouth, by drinking from a Collection Tube. This [safe] 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 of the device and the detached head is then dropped carefully into the Collection Tube containing the mixture of Stabilizing Rinse Solution and saliva. The Collection Tube and specimen are then immediately processed to extract DNA for downstream applications or shipped to a remote laboratory for isolation of DNA. For more detailed instructions on the use of the DNA•SAL™ Salivary DNA Collection Device, please see the Instructions for Use section below.

NOTE: For extraction of DNA from saliva samples collected using the DNA•SAL™ Salivary DNA Collection Device, 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
Reagents for Ethanol Precipitation for DNA Isolation [50 Preparations]	DNAS-501

Kit Contents

	Number
DNA•SAL™ Salivary DNA Collection Device]	1 Each
Collection Tube (Containing Stabilizing Rinse Solution)	1 Tube
Product Insert	1
Envelope (optional)	1

Store at Room Temperature 4-30 ° C

Instructions for Use

PLEASE READ THE COMPLETE INSTRUCTIONS BEFORE PROCEEDING TO COLLECT ORAL FLUIDS / SALIVA USING THE DNA•SAL™ DEVICE. FAILURE TO FOLLOW THESE INSTRUCTIONS CAREFULLY COULD PRODUCE LESS THAN SATISFACTORY RESULTS.

1. Allow 10 minutes after eating or drinking before sample collection.

2. Pool saliva in the mouth and ensure the inside of the cheeks are moist with saliva.

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

4. Take the DNA•SAL™ Salivary DNA Collection Device and place in the mouth with the Collection Teeth perpendicular to the inside of the cheek, towards the LOWER end of the inside of the cheek where the cheek meets the gum line [Image 2].

5. Place a finger firmly on the OUTSIDE of the cheek [to act as a resistance] while collecting the sample and rake the Collection Teeth with pressure along the inside of the cheek area for a minimum of 30 seconds [Image 3]. At this point the Collection Area of the DNA•SAL™ Salivary DNA Collection Device may visually include collected cellular material and saliva. The appearance of this cellular material and saliva 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 subsequent rinsing. Recommended raking time is a minimum of 30 seconds.

6. Remove the device from the mouth and hold in one hand.

7. Using the other hand, pour the contents of the Collection Tube [2 mL of a safe Stabilizing Rinse Solution] into the mouth and “swish” around for 10-15 seconds. DO NOT SWALLOW. After 10-15 seconds, expectorate [“SPIT BACK”] the mixture of Stabilizing Rinse Solution and saliva back into the Collection Tube [Image 4].

8. 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 [Image 5] until the Collection Head of the DNA•SAL™ Device drops off and into the Collection Tube.

9. Discard the Device Handle and screw the Cap of the Collection Tube down tightly to secure the Sample [Image 6].

10. Shake the Collection Tube [now containing a mixture of Stabilizing Rinse Solution, saliva and cells] vigorously for 15 seconds to mix the Stabilizing Rinse Solution and Sample [Image 7].

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

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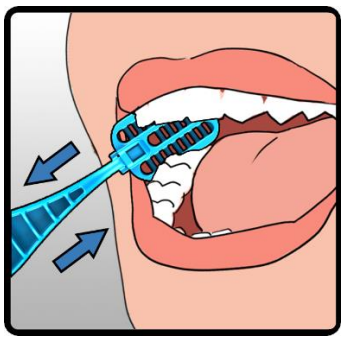

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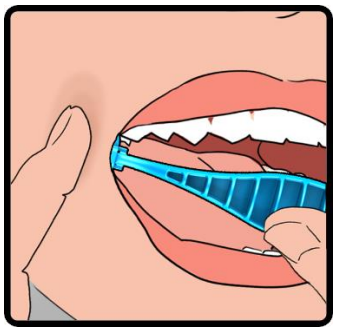

4.

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Performance Data

DNA•SAL™ Salivary DNA Collection Device Performance Characteristics

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 stabilizing agents.

As part of the validation process, DNA harvested using the DNA•SAL™ Salivary DNA Collection Device was evalated for three important performance characteristics- quantity recovered, quality [purity] and sample stability in a series of three experiments carried out by independent investigators.

1.) Quantity of Isolated DNA [Pre- and Post- Extraction]

The DNA•SAL™ Salivary DNA Collection Device provides a mixture of saliva, epithelial cells and Stabilizing 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 Device 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.

Results:

The following results were observed from a total of eight [n=8] samples:

Average Concentration (in µg / mL) of DNA obtained based on a specimen size of 500µl using an Ethanol precipitation DNA isolation protocol = 123.6 µg/mL.

Average Concentration (in µg/mL) 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.

2.) 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 greater than 1.5.

An independent evaluation of DNA purity following isolation of DNA from samples collected using the DNA•SAL™ Salivary DNA Collection Device was assessed using eight (n=8) samples collected and stored in the Oasis Diagnostics® Stabilizing Rinse Solution provided with each DNA•SAL™ Salivary DNA Collection Device prior to analysis.

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.

Results:

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. For further information, please contact Oasis Diagnostics®.

3.) Stability

In order to assess the stability of salivary samples collected using the DNA•SAL™ Salivary DNA Collection device, three (3) samples were collected according to the instructions provided earlier [Instructions for Use].

After rinsing the mouth with the Stabilizing Rinse Solution, the solution was expectorated [“spitted back”] into the Collection Tube provided and stored at ambient temperature [15-30°C]. Samples of this specimen were aliquotted and tested immediately [Day 0] and subsequently at Days 1,3,5,10,20 and 30 days and checked for DNA degradation using agarose gels / gel electrophoresis. All samples showed no degradation up until and including Day 30 indicating that the Stabilizing Rinse Solution confers stability of a minimum of 30 days on DNA.

4.) 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 Device 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 this experimental work 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 Device and DNA isolation using established DNA extraction kits provides an acceptable method of sample purification as an inital step prior to PCR testing.

Advantages of the Oasis Diagnostics® DNA•SAL™ Salivary DNA Collection Device and Companion Salivary DNA Extraction Kits

• Oral samples collected using the DNA•SAL™ Salivary DNA Collection Device [DNAS-102] are stable for long periods of time [minimum 30 [thirty] days] at room temperature in the Oasis Stabilizing Rinse Solution.

• Painless, non-invasive collection.

• High quality, high yield genomic DNA.

• Simple to use.

• User-friendly protocol for potential home based collections.

• Appropriate for pediatric and geriatric populations.

• Rapid and simple processing using commonly available ethanol precipitation, spin-column and 96-well microplate formats.

• DNA extraction can be done on as little as 100 µL of saliva / cells collected using the DNA•SAL™ Salivary DNA Collection Device.

Precautions and Notes

Please take the following precautions when collecting samples using the DNA•SAL™ Salivary DNA Collection Device:

1. Ensure that the Collection Tube containing the Stabilizing Rinse Solution is placed on a flat surface.
2. When closing the Collection Tube, please ensure that the lid is tightly fastened.
3. Avoid introducing any foreign objects into the Collection Tube after opening.

Ordering Information

Product Description	Catalog Number
DNA•SAL™ Salivary DNA Collection Device	DNAS-102

Other Accessories

Product Description	Catalog Number
Oasis Mini•SAL™ Salivary DNA Isolation Kit [Spin Column Method, 30 Preparations]	DNAX-504
Oasis Midi•SAL™ Salivary DNA Isolation Kit [Spin Column Method, 30 Preparations]	DNAX-505
Stabilizing Rinse Solution [100mL]	DNAS-504
DNA/RNA Stabilizing Agent (for long term shelf life)	

Final Note

Rev: 022316

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 e-mail to

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