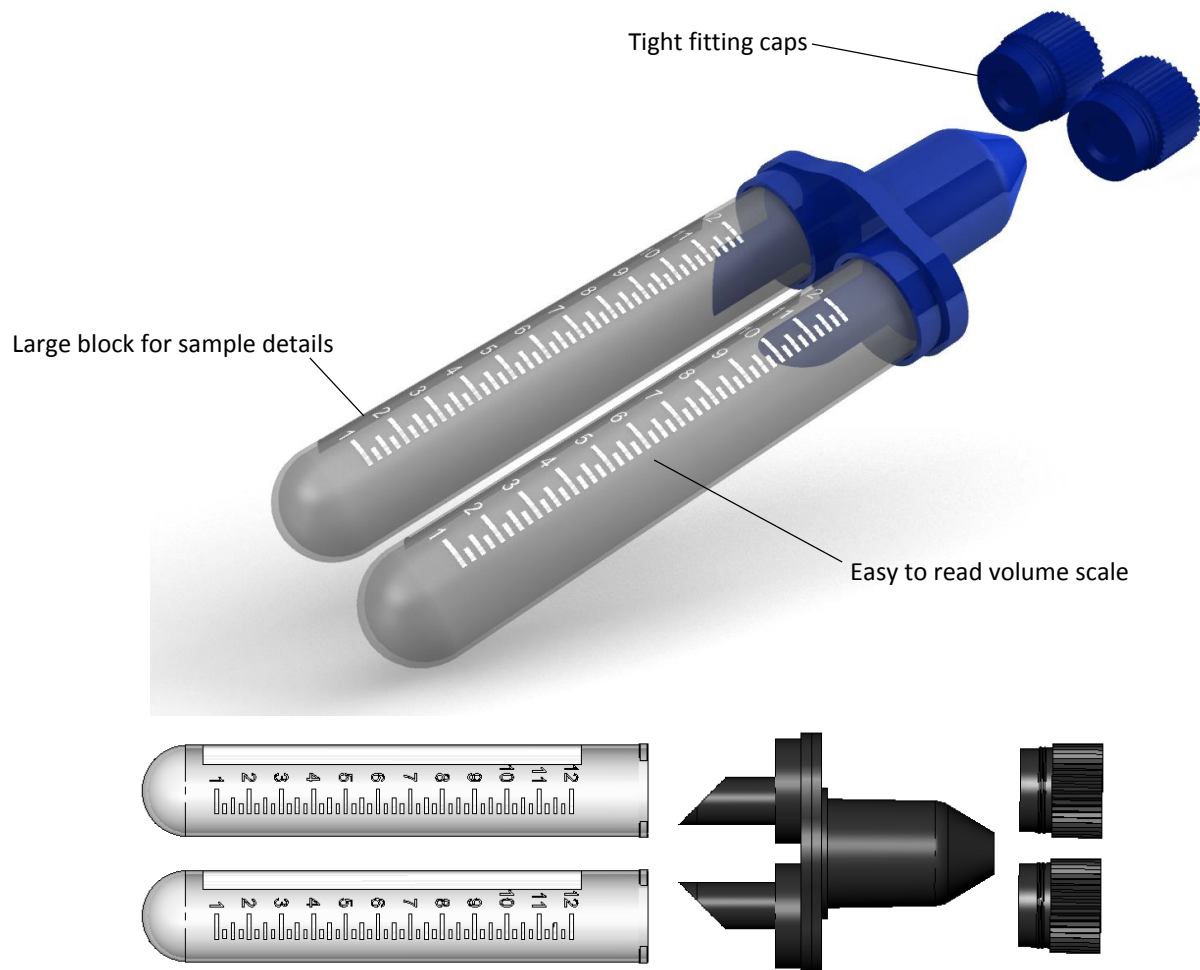


UltraSal-2™

Split Sample Saliva Collection Device

Catalog Number: USAL-501



Intended Use

The UltraSal-2™ saliva collection device is for the collection of oral fluid. UltraSal-2™ automatically splits the sample into two aliquots. One tube can be used for testing, and the second tube can be used for confirmation of results or stored for possible future use.

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

Introduction

Saliva is becoming an increasingly attractive bodily fluid for the easy, noninvasive and cost-effective replacement of traditional blood sampling and, as a result, a number of tools have been developed that allow for the simple collection of various components of saliva or “whole saliva”. A number of these have found specific and important applications within the expanding market for salivary diagnostics.

Despite the availability of a number of available oral fluid collection devices, there are few that offer standardized saliva collection in a short time, with a built-in mechanism for splitting samples. UltraSal-2™ incorporates both a novel sample collector with splitter built into the device, and provides a rapid method for large volume sampling of oral fluids/whole saliva for a variety of applications.

Principles of the Device

The UltraSal-2™ is a proprietary, patent-pending device intended for the standardized collection of whole saliva.

In order to collect a specimen, subjects are requested to ‘expectorate’ [spit] into the mouthpiece of the collection device, where saliva is then channeled into two separate tubes. Sample adequacy can be determined easily via the volume scale on the sides of the collection tubes.

Materials Provided

1. UltraSal-2™ saliva collection mouthpiece and base
2. Two graduated sample collection tubes
3. Two blue tube caps

Materials Recommended but not Provided

1. Disposable exam gloves
2. Rack or holder for tubes and/or assembled devices
3. Container for proper disposal of used materials

Instructions for Use

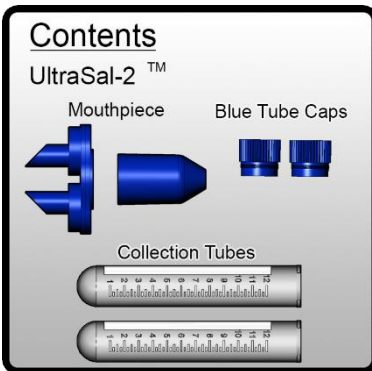
PLEASE READ THE COMPLETE INSTRUCTIONS BEFORE PROCEEDING TO COLLECT ORAL FLUIDS / SALIVA USING THE UltraSal-2™ DEVICE. FAILURE TO FOLLOW THESE INSTRUCTIONS CAREFULLY COULD PRODUCE LESS THAN SATISFACTORY RESULTS.

Do not eat, drink, smoke, or use oral hygiene products for at least 10 minutes before you start the collection process.

During this time review the detailed instructions on the UltraSal-2™ Saliva Collection Device insert below.

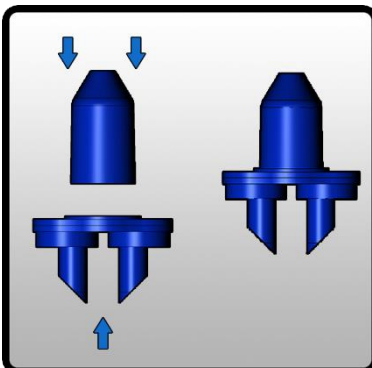
Step-by-Step Instructions

1.



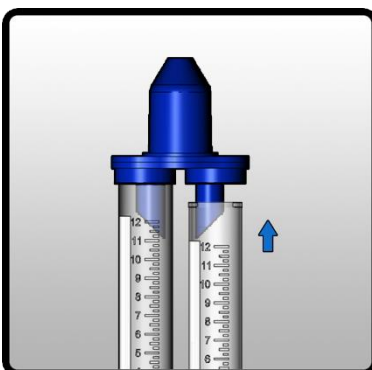
In preparation for oral fluid (saliva) collection place contents on a clean and dry surface.

2.



Wearing disposable gloves, snap the mouthpiece securely inside the large ring on top of the base. Label collection tubes as required with sample ID information.

3.



Attach the two Collection Tubes to the bottom of the UltraSal-2™ base by sliding one tube over each outlet and pushing them firmly into the bottom of the base until they snap securely in place.

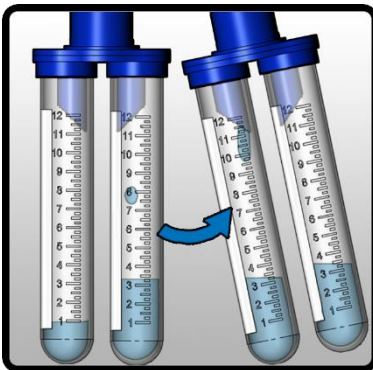
4.



Hold the assembled UltraSal-2™ in a manner that keeps the Collection Tubes close to vertical. Pool oral fluid in the mouth, then place the hole in the top of the mouthpiece to the lips and expel the oral fluid through the hole.

NOTE: Do not blow into the device.

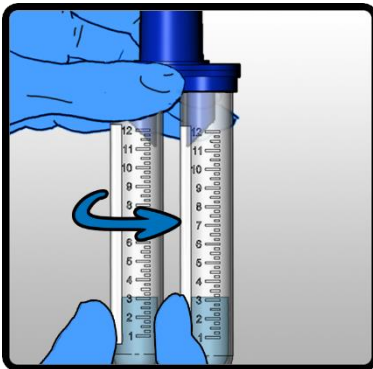
5.



Rotate or tip the device as necessary to direct the flow of oral fluid into one or both tubes, as desired.

NOTE: Collection must be stopped if the level of fluid or bubbles touches the lower tip of the outlets.

6.



Gently remove the Collection Tubes by holding the UltraSal-2™ base in one hand, grasping a tube in the second hand, and twisting the tube gently from side to side until the tube separates from the base.

7.



Firmly insert a blue tube cap into each Collection Tube for storage or transportation. Discard the UltraSal-2™ mouthpiece and base in an appropriate manner.

Additional Tips for Successful Use:

1. The time required to collect a sufficient sample volume for testing will vary among individuals. For many people, about 2 mL can be collected per tube in 3 to 5 minutes. Individuals who have a dry mouth may require additional collection time.
2. The donor should not block the vent holes located in the UltraSal-2™ base above each of the collection tubes.
3. Oral fluid will generally flow into the collection tubes without assistance. Occasionally, fluid or bubbles may pool inside the mouthpiece. Should this occur, blowing gently into the mouthpiece may help speed the flow into the collection tubes.
4. During use, the flow of oral fluid may favor one of the tubes. The UltraSal-2™ collector can be rotated and/or tipped to control flow into the collection tubes. Positioning one collection tube slightly lower than the other will result in more oral fluid flowing into the lower tube.
5. Graduation lines on the collection tubes allow the amount of oral fluid to be estimated as it is collected. Typically, the bubbles (foam) that collect in the tubes on top of the liquid sample will collapse with time.

NOTE: Some individuals may produce oral fluid that contains large amounts of bubbles (foam). If the tubes fill with bubbles during collection, gently tapping the bottom of the collection tubes on a solid surface may speed settling of the bubbles. Collection of additional oral fluid can be continued.

6. The samples should be stored in a manner appropriate for the intended assay. Possible alternatives include addition of preservative, refrigeration, or freezing. Note: The UltraSal-2™ saliva collection device contains no preservative.

Precautions and Notes

Please take the following precautions when collecting samples using the UltraSal-2™ Split Sample Saliva Collection Device:

1. Testing or diagnosis of the collected samples should be performed in a laboratory setting by skilled professionals.
2. No claims are made for recovery or detection of any specific analyte.
3. No claims are made for preservation or storage conditions.
4. The proper performance of the UltraSal-2™ is based upon use of the graduated collection tubes and caps available with the UltraSal-2™ listed on page 1. No performance claims are made when other tubes or caps are substituted.
5. All used device components should be handled carefully at all times in case infectious agents are present.

Ordering Information

“Ready to Use” Collection Device:

Catalog No.	Product Description
US2	1- UltraSal-2™. Ready to Use Saliva Collection Device – Just snap on mouthpiece. Packaged individually. Minimum order – 10 devices per order.

Want to save money? Buy in bulk!

Catalog No.	Product Description
US2-10	UltraSal-2™ 10 pack – Includes: 10 mouthpieces and 10 bases, 20 sample collection tubes (17 mm x 100 mm), and 20 caps (17 mm). Assembly required.
US2-50	UltraSal-2™ 50 pack – Includes: 50 mouthpieces and 50 bases, 100 sample collection tubes (17mm x 100 mm), and 100 caps (17 mm). Assembly required.

Final Note

UltraSal-2™ and Oasis Diagnostics® are trademarks of Oasis Diagnostics® Corporation.

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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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