

Versi·SAL[®]

Oral Fluid (Saliva) Collection Device

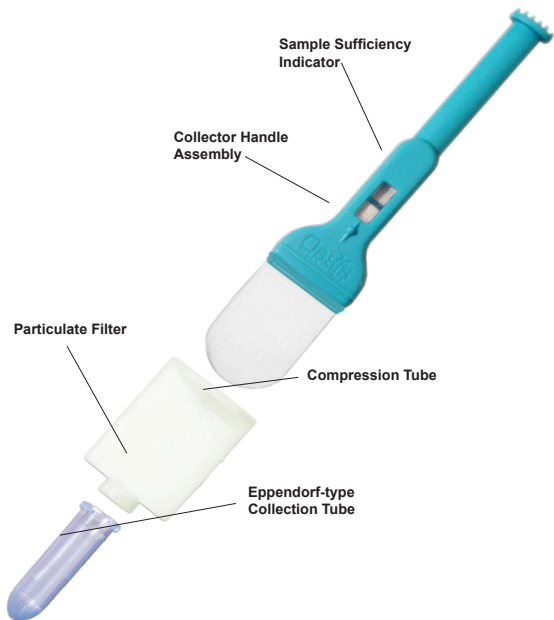


Instructions for Use

Oasis
DIAGNOSTICS
Pioneering Oral Fluid Diagnostic Solutions

Versi•SAL®

Oral Fluid (Saliva) Collection Device



Intended Use

The Versi•SAL® Oral Fluid (Saliva) Collection Device is intended for the controlled, standardized collection and transportation of oral fluid (saliva) specimens for subsequent disease testing, analysis or research applications. The devices do not provide any diagnosis of disease.

Introduction

The collection of alternative specimens such as urine, hair, sweat, tears, saliva and others is growing in importance as an alternative to blood sampling. A number of devices exist that allow for the collection of various forms of oral fluid or saliva and each has specific application in the growing market for salivary diagnostic testing.

Despite the availability of a number of available oral fluid collection devices, there are few offering standardized collection with a means of confirmation of sample sufficiency. Versi-SAL® incorporates both a novel Sample Volume Adequacy Indicator built into the device handle and provides a suitable quantity of oral fluids / whole saliva for a variety of applications.

Principles of the Device

The Versi-SAL® Oral Fluid / Saliva Collection Device is a proprietary, Patented device intended for the standardized collection of whole saliva, from under the tongue.

In order to collect an adequate specimen, subjects / patients are requested to “pool” saliva under the tongue to facilitate faster collection times. The Versi-SAL® device features an absorbent pad material, which is placed under the tongue to collect the sample.

Materials Provided

Versi-SAL® Oral Fluid Device with single absorbent collection pad and sample sufficiency indicator.

Single Sample Compression Tube.

Materials Required but not Provided

1. For the Versi•SAL® Oral Fluid Collection Device, standard Eppendorf® microcentrifuge collection tubes (or equivalent) are required. As an alternate the user may substitute alternate collection tools, provided the user validates the collection method used for the specific, intended application
2. Standard Eppendorf (or equivalent) tube rack

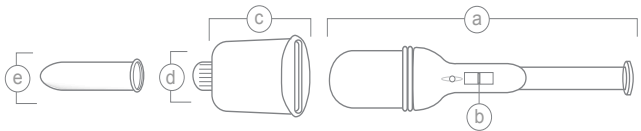
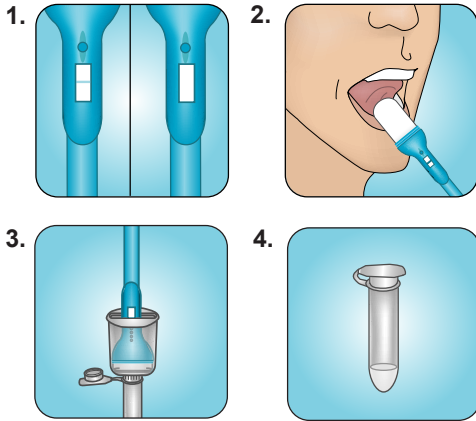
Instructions for Use

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

Versi•SAL® incorporates a highly absorbent collection pad, which soaks up saliva very quickly and efficiently. In order to facilitate faster sample collection, remove the device from the mouth occasionally (approximately every 30 seconds), if required. Immediately observe the Sample Volume Adequacy Indicator while “pooling” further saliva under the tongue, then promptly replace the Versi•SAL® device under the tongue and resume collecting saliva until the Sample Volume Adequacy Indicator changes, signifying sufficient saliva sample has been collected.

Step-by-Step Instructions

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



1. Observe the appearance of the Sample Volume Adequacy Indicator, (b) (see picture 1, left side).
2. Attach a standard 2mL graduated Eppendorf tube (e, available as an optional component, Catalog Number EPDF-201) to the outlet (d) of the compression tube (c) provided.
3. Ask subject / donor to “pool” saliva in the mouth, under the tongue.
4. Take the Versi•SAL® collection device (a) and place the absorbent pad material end UNDER the tongue (See picture 2) and continue collecting oral fluids until the Sample Volume Adequacy Indicator (b) changes (approximately 1-2 minutes). Note 1: At this point the blue-coloured line will have disappeared indicating adequate volume of saliva has been collected for subsequent analysis, testing or storage for later analysis. (See picture 1, right side). Note 2: It is acceptable to remove the device from the mouth to observe the Sample Volume Adequacy Indicator (b) and to carry out further “pooling” of saliva to reduce sample collection time. If this is done, resume sample collection as swiftly as possible.
5. Holding the Versi•SAL® collection device upright (in a vertical position) with one hand, push the Versi•SAL® device (a) down into the compression tube (c) with the other hand until the device fits into the compression tube housing (c) and continue to push until saliva begins to flow into the Eppendorf tube (e), or alternate collection vessel.

Note: Use enough force to facilitate saliva flow,
(See picture 3).

6. Saliva will flow from the absorbent material through the outlet of the compression tube (d) and into the Eppendorf tube (e). Once no further compression is possible, wait approximately 30 seconds for the saliva sample to drain into the Eppendorf tube (e), then remove tube (e) from the compression tube (c) and close the cap. The saliva specimen is now ready for immediate testing or transportation to a laboratory for further analysis.

Use the saliva samples collected for immediate (point-of-care testing) applications, send to a qualified laboratory for additional testing or store in a freezer at -20° or -70° Celsius for later analysis
(See picture 4).

Precautions and Notes

1. Devices are for single use only. Used devices and samples should be treated as potentially infectious and disposed of in appropriate biohazardous waste containers.
2. Do not use devices beyond the expiration date printed on the pouch.
3. Prior to use, record patient / subject information on the collection tube.
4. During sample collection, ensure that the subject does not chew or suck on the absorbent collection pad.
5. Collect until the Sample Volume Adequacy Indicator 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 15 minutes discard the device and begin a further collection with a fresh device.

6. As an option, oral fluids (saliva) may be removed from the Versi•SAL® collection device by vortexing or centrifugation.
7. The absorbent material used to collect specimens contains no added salts, preservatives or other agents.
8. Testing of oral fluids collected using the Versi•SAL® Oral Fluid Collection Device should be done according to validated protocols provided by diagnostic test manufacturers. Oasis Diagnostics® Corporation provides no warranty as to the suitability of the Versi•SAL® Oral Fluid Collection Device, for any given application, other than the Intended Use described herein.
9. Versi•SAL® Oral Fluid Collection Devices are provided in non sterile form but may be provided in sterile form upon request.
10. Store at room temperature (15-30°C) until the expiration dating written on the exterior of the pouch.
11. The Versi•SAL® Oral Fluid Collection Device does not diagnose any disease.

Ordering Information

Versi-SAL® Collection Devices are sold in units of 50 collection devices per box and 10 boxes (500 devices) per shipping box (see Ordering Information below).

Versi-SAL® Oral Fluid Collection Device

Catalog Number: VSAL - 401

Qty: 50

Eppendorf Tubes (2mL)

Catalog Number: EPDF - 201

Qty: 500

Final Note

Versi-SAL® Devices are provided in different custom formats depending upon the required application. Please contact Oasis Diagnostics® for further details.

Manufactured for Oasis Diagnostics® Corporation in the United States

This device is protected by US and EU Patents including US Patent Numbers

7,618,591

7,927,548

8,273,305 and others

Rev: 062913 - 01



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