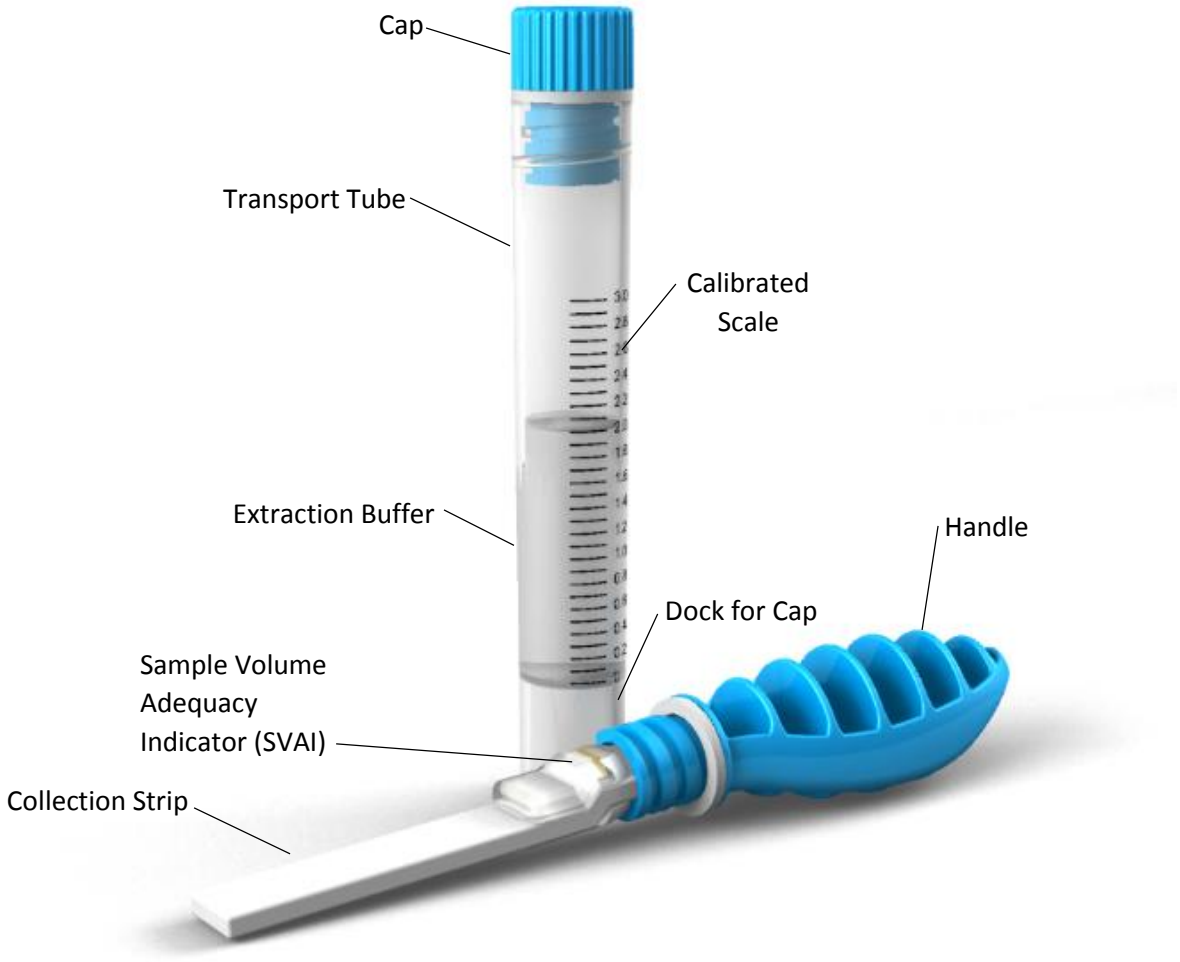
Accu•SAL™

ORAL FLUID COLLECTION SYSTEM

Catalog Number# ACSL-201



Intended Use

Accu•SAL™ is an 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.

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

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 oral fluid collection devices, there are few offering standardized collection of oral fluids for drug and drug metabolite testing with a means of confirmation of sample sufficiency. Accu•SAL™ incorporates a novel Sample Volume Adequacy Indicator (SVAI) built into the device handle and provides a suitable quantity of oral fluids (whole saliva) for a variety of drug testing applications. In addition the device provides a critical means of determining sample dilution when insufficient sample is collected.

Principles of the Procedure

The Accu•SAL™ Oral Fluid Collection System is a proprietary patented device for the standardized collection of whole saliva from the side of the tongue in the mouth. In order to collect an adequate specimen, it is recommended that patients/subjects “pool” saliva in the mouth just prior to sample collection to facilitate faster collection times. The Accu•SAL™ Oral Fluid Collection System features a Collection Strip comprised of an Absorbent Pad material, which is placed in the pool of saliva under the tongue and adjacent to the teeth to collect the sample. After 1-2 minutes, a Sample Volume Adequacy Indicator (SVAI) changes appearance signifying sufficient saliva has been collected for subsequent analysis. The Collection Strip is then transferred to a secondary tube for transportation to a laboratory. Upon receipt at the laboratory the sample may be removed by vortexing or centrifugation if it has received insufficient inversion during transit (See Sample Analysis and Extraction Instructions, Paragraph 4) and is then ready for drug 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™ Oral Fluid Collection Device can be accurately calculated from the amount of liquid displaced in the Accu•SAL™ Buffer Tube when the Collection Strip is introduced into the Transport Buffer. A detailed description of this procedure is provided on Page 5 in the “Sample Analysis and Extraction” section.

Materials Provided

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

Materials Required but not Provided

(1) Shipping materials if required

Instructions for Use

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

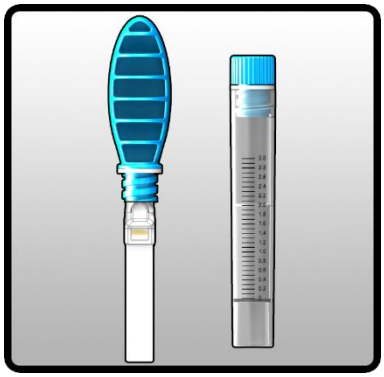
Do not eat, drink, smoke, or use oral hygiene products for at least 10 minutes before you start the collection process.

Review the detailed instructions in the Accu•SAL™ Oral Fluid Collection System Package Insert below, particularly the illustrations showing the appearance of the SVAI before and after sample collection (See Figures 2 and 4, next page).

Step-by-Step Instructions

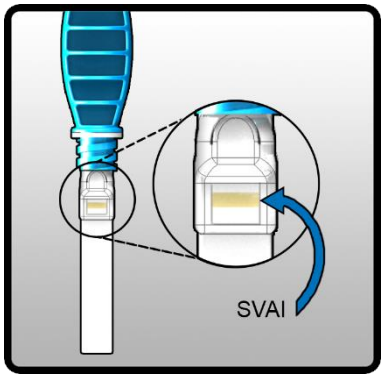
Note: Ensure collection is continued until the SVAI visually changes, confirming sample sufficiency.

1.



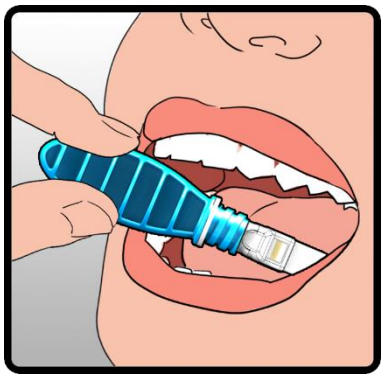
Open the package containing the Accu•SAL™ Oral Fluid Collection system. Remove the Collection Strip by the Handle.

2.



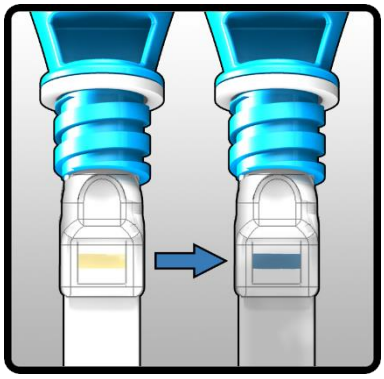
View the SVAI just beneath the handle, with the front of the handle facing you, by looking directly at the SVAI with the strip held at a slight angle away from you.

3.



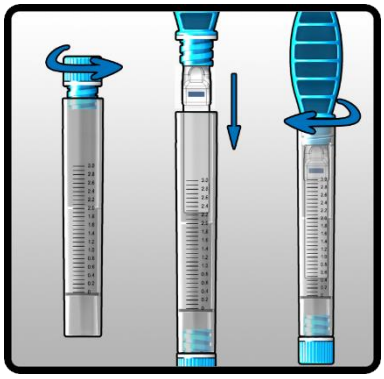
While holding the Handle, place the Collection Strip in the mouth. Allow the Collection Strip to absorb saliva that has been pooled. Continue to pool and absorb saliva while moving the Collection Strip further into the mouth with the goal of saturating the entire pad.

4.



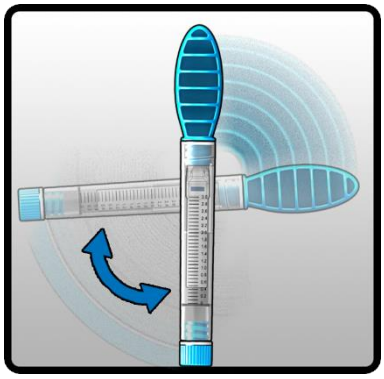
Remove the Collection Strip from the mouth every 15-20 seconds and continue collecting until the SVAI changes from yellow / green to blue (see left). Sample collection is now complete.

5.



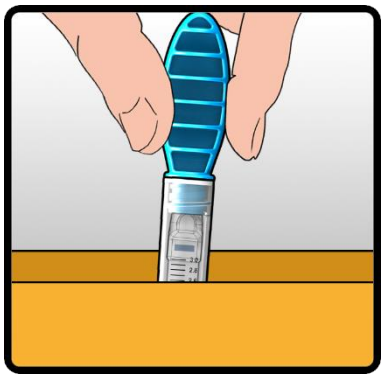
Remove the cap from the Transport Tube containing the Extraction Buffer and push the cap into the dock located in the bottom of the Transport Tube. Place the saturated pad connected to the Handle into the Transport Tube containing the Extraction Buffer, and screw the cap tightly onto the Transport Tube.

6.



Invert Transport Tube 20-40 times.

7.



If the sample is to be analyzed at the point of collection, see the attached instructions, otherwise, place the sealed Transport Tube containing the Collection Strip and Extraction Buffer into an appropriate shipping container.

Sample Analysis and Extraction Instructions

1. Recovery of analytes: Recovery of analytes from the Accu•SAL™ Oral Fluid Collection Device will depend upon the structure of the analyte being tested. Some analytes bind very 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.

2. Whole saliva dipping recovery measurements may, depending upon reporting requirements, need to be corrected for the amount of saliva absorbed onto the pad. The maximum saliva load by oral (mouth) collection is 1.0 – 1.1 mL of saliva. This will result in a 1:3 dilution with the 2.0 mL of Extraction Buffer provided at complete extraction (see point 4

below). Dipping into whole saliva usually results in lower recovery than oral [mouth] collection, and typically results in higher dilutions.

3. The quantity of saliva obtained from any collection can be determined using the graduated scale on the side of the Transport Tube.

(i) Once the loaded Collection Strip has been placed into the Transport Tube and the Handle has been screwed down tightly and inverted 20-40 (twenty to forty) times, allow contents of the Transport Tube to settle. Make sure all fluid is settled below and not trapped in the Handle or the sides of the Transport Tube, by tapping or flicking the Tube.

(ii) Remove the Handle/Collection Strip from the Transport Tube, ensuring that any loose fluid is returned to the tube. Discard the handle/collection strip.

(iii) Turn the Transport Tube so the scale is visible, and level with the naked eye.

(iv) Determine the load volume by reading the scale value (SV) that corresponds to the meniscus level of the Extraction Buffer. Use the lines at 100µL intervals to judge to within 25-50µL. The actual Measured Saliva Load (MSL, in mL) and the corrected dilution can then be calculated using the equation below:

Dilution Factor	MSL Calculation	Extraction Buffer Provided (mL)	Corrected Dilution
1:3	SR - 0.87	2.00	(MSL + 2.00) / MSL

For example:

If the scale value = 1.9, the MSL would equal 1.90 – 0.87 = 1.03 mL
At an MSL of 1.03 mL the dilution would be 1.03 + 2.00 / 1.03 = 2.94 or within 2% of a 1:3.

(vi) Rarely will the SVAI turn blue with load volumes less than 0.5 mL. Low load volumes may occasionally result in solutions that are too dilute to be measured within the operating parameters of the method. A range of acceptable load values, with or without dilution correction, can be established within the collection protocols described in this package insert. In rare situations, where it is not possible to establish the correct measured saliva load and / or

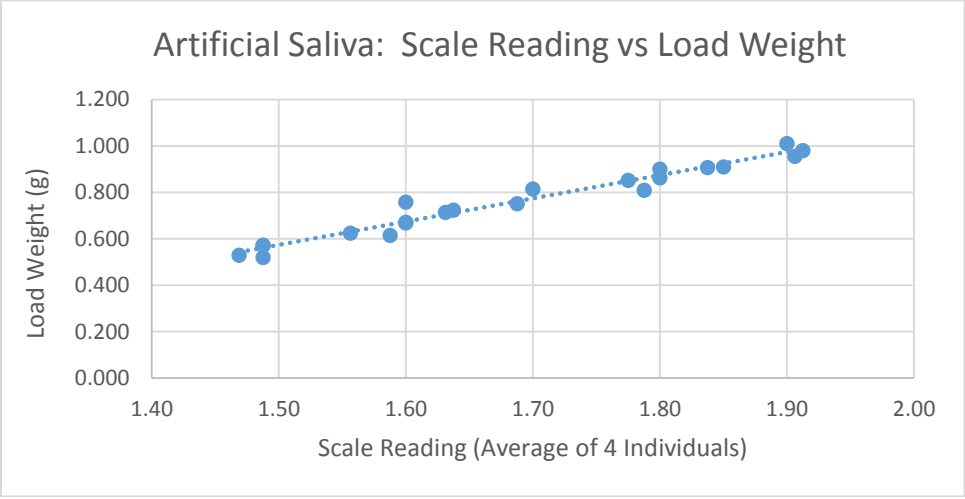
corrected dilution, it is recommended that the collection process should be repeated with a new device.

4. Absolute recovery of saliva from the Accu•SAL™ 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.

Product Performance Characteristics

Scale Read Accuracy and Precision, Gravimetric Comparison

22 Samples were tested using artificial saliva over a load range of 0.5 to 1.0 mL. The scales were read by 4 individuals and the scale readings were averaged. The average % error was 1.2% with an average variation of +/0.02 mL (CV).



Donor Saliva Recovery

21 Individual samples were loaded until the SVAI changed to a crisp blue line. The average load was 0.82 mL with a range of 0.64 – 0.92 mL. The average collection time was 68 seconds with a range of sampling times from 22 seconds to 360 seconds. The scales were read by 4 individuals and the scale readings were averaged. The average % error was 0.6% with an average variation of +/- 0.01 mL (CV).

Donor ID	Load Weight (g)	Scale Reading	Calculated Load (ml)	% Recovery
1	0.824	1.70	0.83	101%
2	0.830	1.70	0.83	100%
3	0.820	1.65	0.78	95%
4	0.914	1.81	0.94	103%
5	0.874	1.70	0.83	95%
6	0.749	1.59	0.72	96%
7	0.919	1.73	0.85	93%
8	0.872	1.70	0.83	95%
9	0.811	1.70	0.83	102%
10	0.640	1.50	0.63	98%
11	0.653	1.50	0.63	96%
12	0.816	1.70	0.83	102%
13	0.872	1.80	0.93	107%
14	0.859	1.70	0.83	97%
15	0.824	1.70	0.83	101%
16	0.830	1.70	0.83	100%
17	0.775	1.66	0.79	102%
18	0.841	1.76	0.89	106%
19	0.851	1.71	0.84	99%
20	0.832	1.73	0.85	103%
21	0.832	1.66	0.79	95%
Average	0.82	1.69	0.82	99%
Std Dev	0.068	0.076	0.076	0.037
% CV	8.3%	4.5%	9.3%	3.8%

KIT COMPONENTS

Catalog Number	Item
ACSL-201	Accu•SAL™ Oral Fluid Collection Device [2.0 mL Fill, 1:3 Dilution]

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 manner.

2. Do not use devices beyond the expiration date printed on the pouch.

3. Prior to use, record patient / subject information on the Transport Tube.

4. During sample collection, ensure that the subject does not chew or suck on the absorbent Collection Strip.

5. Collect until the SVAI provides a visual indication that the required volume has been collected. Typical collection time is 1 – 3 minutes. If the requisite sample has failed to collect within 10 minutes discard the device and begin a further collection with a fresh device.

6. The absorbent Collection Strip used to collect specimens contains no added salts, preservatives or other agents.

7. Testing of oral fluids collected using the Accu•SAL™ Oral Fluid Collection Device should be done according to validated protocols provided by test kit manufacturers. Oasis Diagnostics® Corporation provides no warranty as to the suitability of the Accu•SAL™ Oral Fluid Collection Device, for any given application, other than the Intended Use described herein.

8. Accu•SAL™ Oral Fluid Collection Devices are rigorously tested for compliance with United States Pharmacopeia (USP) for non-sterile products but may be provided in sterile form upon request.

9. Store at room temperature (15-30°C) until the expiration date written on the exterior of the pouch.

10. The Accu•SAL™ Oral Fluid Collection Device does not diagnose any disease.

Ordering Information

Accu•SAL™ Oral Fluid Collection Devices are sold in units of 50 collection devices per box and 10 boxes (500 devices) per shipping case (see Ordering Information below).

Accu•SAL™ Oral Fluid Collection Device

Catalog Number: ACSL-201 1:3 Saliva : Buffer Configuration
Qty: 50

Final Note

Accu•SAL™ Devices can be provided in 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: 051016

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

Oasis Diagnostics® Corporation

15720 NE 31st Avenue

Vancouver WA 98686 USA

Phone: (360) 546-1563

FAX: (360) 546-1581

Website:

E-mail: info@4saliva.com