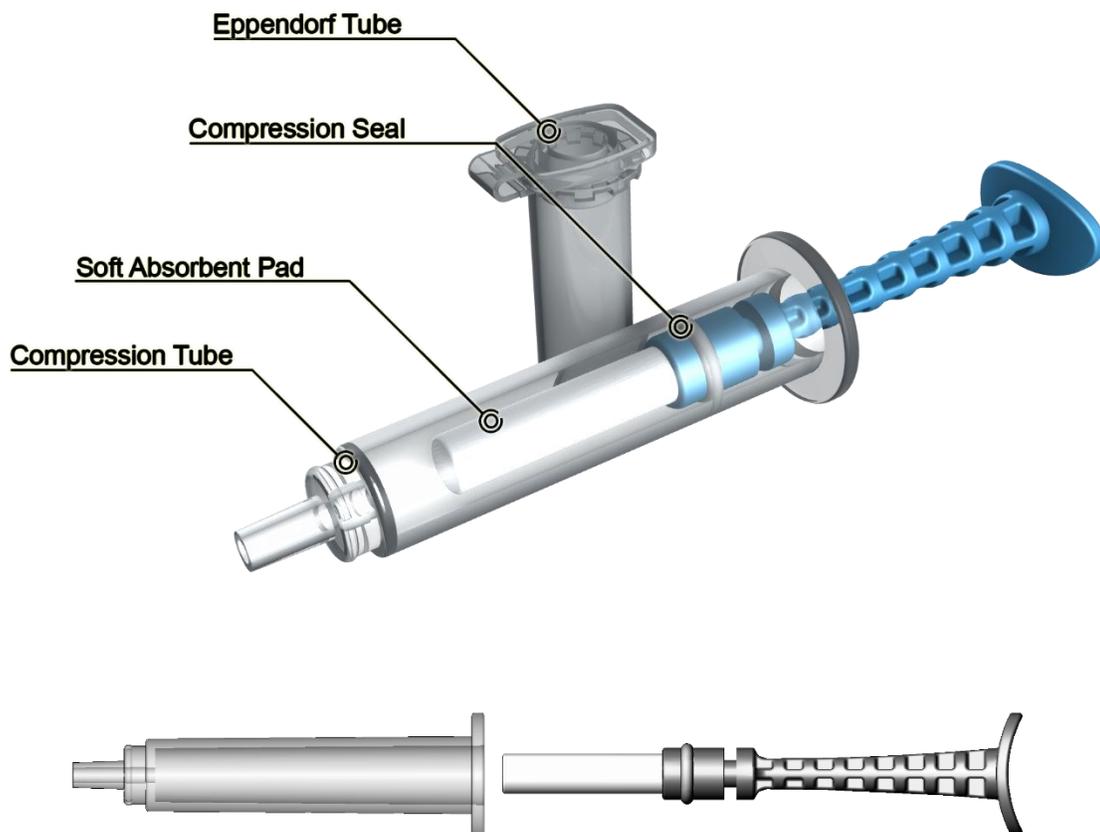


Micro•SAL™

Infant Saliva Collection System

Catalog Number MRSAL-402



Intended Use

The Micro•SAL™ Infant Saliva Collection Device is intended for the controlled, standardized collection and transportation of oral fluid (saliva) specimens from Infants for subsequent testing, analysis, or research applications. The devices do 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

Saliva is becoming an increasingly attractive bodily fluid for the easy, noninvasive and cost-effective replacement for 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 (1.2).

Despite the availability of a number of available oral fluid collection devices, there are few that offer standardized saliva collection that are suitable for collection of non-invasive samples from infants. The Micro•SAL™ Infant Saliva Collection Device provides a rapid method for simple and effective sampling of oral fluids/whole saliva from infants for a variety of downstream applications.

Principles of the Device

The Micro•SAL™ Infant Saliva Collection Device is a proprietary, patented device intended for the standardized collection of whole saliva from inside the mouths of infants.

The Micro•SAL™ device features a cylindrical absorbent pad that facilitates rapid collection times. Saliva is released from the absorbent pad used to collect the specimen by compressing the pad through a narrow bore tube connected to a standard Eppendorf tube.

Materials Provided

1. Micro•SAL™ Infant Saliva Collection Device.
2. Clear Plastic Compression Tube.
3. One 0.5 mL Eppendorf Tube

Materials Required, but not Provided

1. Timer
2. Preservative, if required.

Instructions for Use

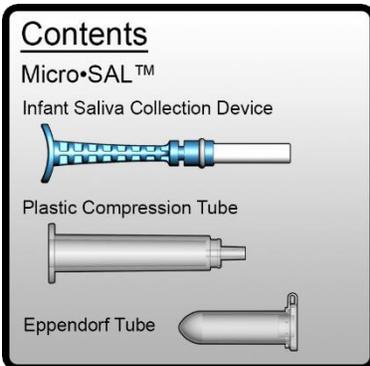
PLEASE READ THE COMPLETE INSTRUCTIONS BEFORE PROCEEDING TO COLLECT ORAL FLUIDS / SALIVA USING THE MICRO•SAL™ DEVICE. FAILURE TO FOLLOW THESE INSTRUCTIONS CAREFULLY COULD PRODUCE LESS THAN SATISFACTORY RESULTS.

Do not allow the infant to eat or drink for at least 5 minutes before starting the collection process.

During this time review the detailed instructions on the Micro •SAL™ Infant Saliva Collection Device Package Insert below.

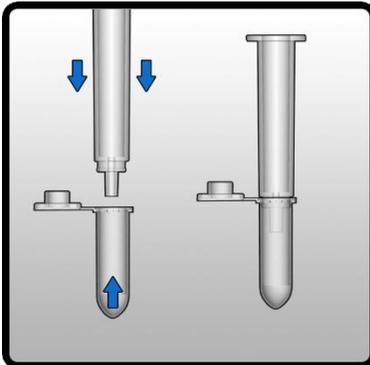
Step-by-Step Instructions

1.



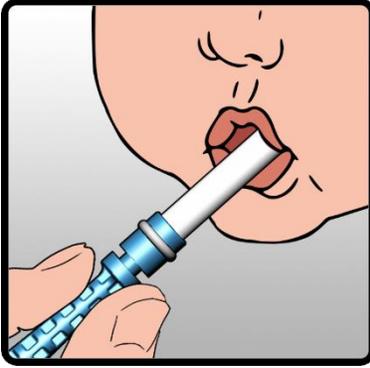
In preparation for collection, place contents on a clean and dry surface.

2.



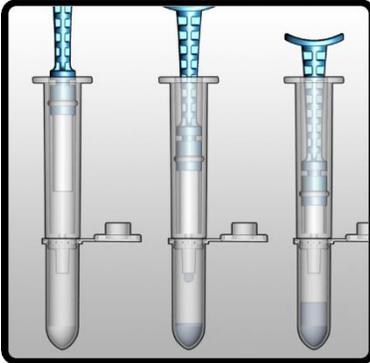
Attach the Eppendorf tube provided to the base of the Plastic Compression Tube firmly.

3.



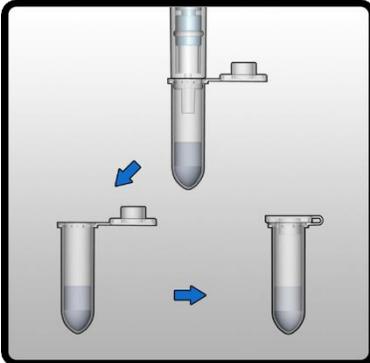
Place the tip end of the white absorbent collection pad of the Micro•SAL™ device into the mouth of the infant where saliva pools, and collect until the pad is saturated.

4.



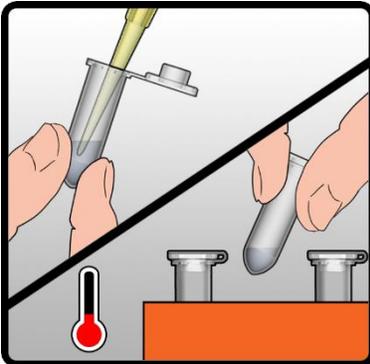
Place the white absorbent pad end into the Plastic Compression Tube holding the Micro•SAL™ device in an upright and vertical position and firmly push the plunger downwards to transfer saliva from the absorbent pad into the Eppendorf Tube. Push and hold for 15 seconds.

5.



Gently remove the Eppendorf Tube from the end of the Plastic Compression Tube. Add preservative (not provided), if required, and close the lid on the tube tightly.

6.



Process the collected sample immediately or store at refrigerated temperatures [depending upon the specific application] until required.

KIT COMPONENTS

<u>Catalog Number</u>	<u>Item</u>
MRSAL-402	MICRO•SAL™ INFANT SALIVA COLLECTION DEVICE
EPDF-202	0.5 mL Eppendorf Tube
Note	The Micro•SAL™ device may include the above collection tube or other options for sample collection.

Precautions and Notes

1. DO NOT ALLOW THE INFANT TO EAT OR DRINK WHILE COLLECTION IS IN PROGRESS
2. DO NOT REUSE OR SUBSTITUTE DEVICE COMPONENTS
3. Devices are for single use only. Used devices and samples should be treated as potentially infectious and disposed of in appropriate biohazardous waste containers.
4. Do not use devices beyond the expiration date printed on the pouch.
5. Prior to use, record subject information on each of the Eppendorf Collection Tubes.
6. During sample collection, ensure that the infant does not chew or suck on the absorbent collection pad.
7. Micro•SAL™ Infant Saliva Collection Devices are provided in non-sterile form but may be provided in sterile form upon request.
8. The absorbent material used to collect specimens contains no added salts, preservatives or other agents.
9. As an option, oral fluids (saliva) may be removed from the Micro•SAL™ collection device by vortexing or centrifugation.
10. Store at room temperature (15-30°C) until the expiration date written on the exterior of the pouch.
11. The Micro•SAL™ Infant Saliva Collection System does not diagnose any disease.

Ordering Information

Micro•SAL™ Infant Saliva Collection Devices are sold in units of 50 collection devices per box and 10 boxes (500 devices) per shipping box (see Ordering Information below).

Micro•SAL™ Infant Saliva Sample Collection System

Catalog Number: MRSAL-402

Quantity: 50 / 500

0.5 mL Eppendorf Tubes

Catalog Number: EPDF-202

Quantity: 100 / 500

Optional Component

Tube Rack

Catalog Number TRAC-001

Quantity: 1

Final Note

Micro•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: 20161122

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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