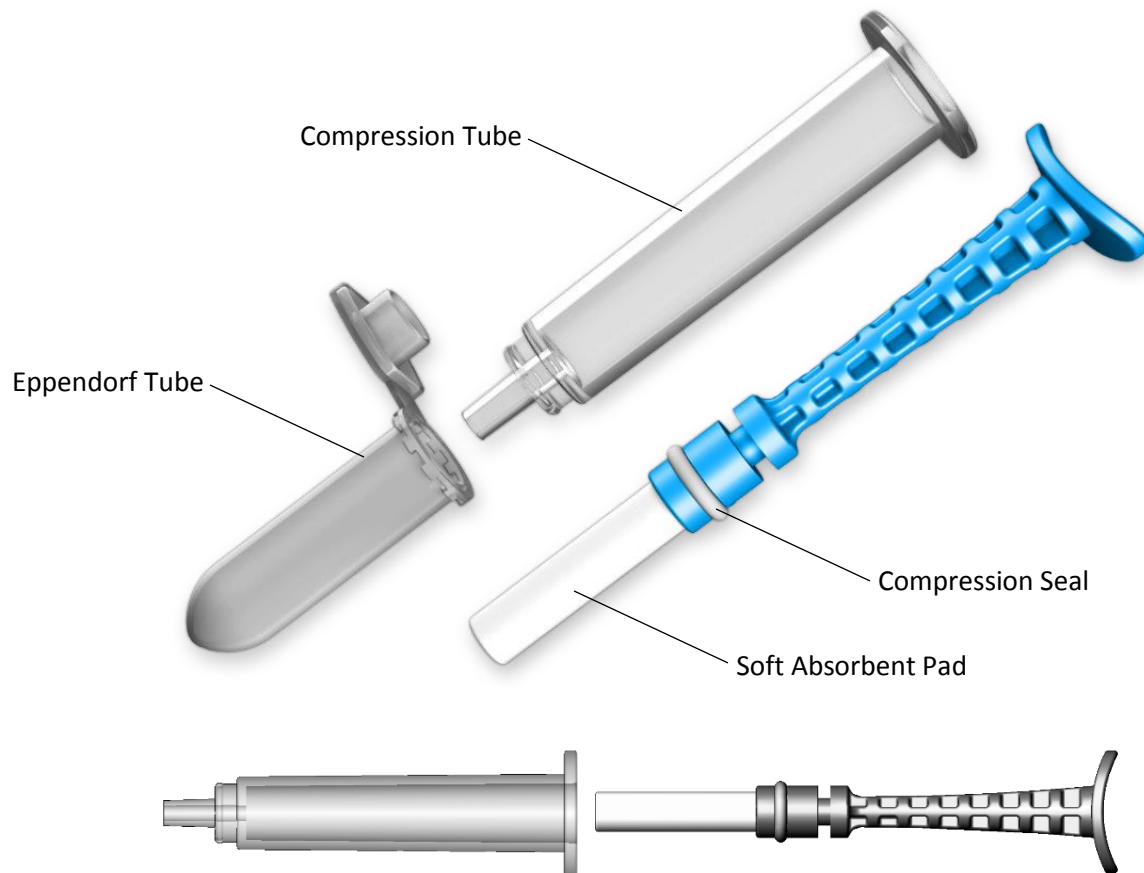


Micro•SAL™

Infant Saliva Collection

Catalog Number MRSAL-402



Intended Use

The Micro•SAL™ Infant Saliva Collection Kit 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.

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 Kit 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 Kit is a proprietary, patented system intended for the standardized collection of whole saliva from inside the mouths of infants.

The Micro•SAL™ Collector 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 Collector
2. Clear Plastic Compression Tube
3. One standard 2.0 mL Eppendorf Tube

Materials Recommended but Not Provided

1. Timer
2. Preservative (if required)

Instructions for Use

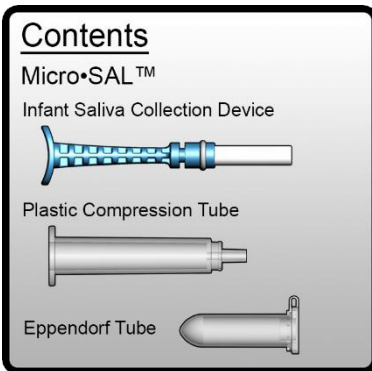
PLEASE READ THE COMPLETE INSTRUCTIONS BEFORE PROCEEDING TO COLLECT ORAL FLUIDS / SALIVA USING THE MICRO•SAL™ INFANT SALIVA COLLECTION KIT. FAILURE TO FOLLOW THESE INSTRUCTIONS CAREFULLY COULD PRODUCE LESS THAN SATISFACTORY RESULTS.

Do not allow the infant to eat or drink for at least 30 minutes before starting the collection process.

Prior to collection, review the detailed instructions on the Micro•SAL™ Infant Saliva Collection Kit Package Insert below.

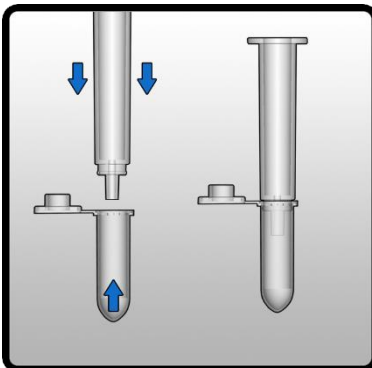
Step-by-Step Instructions

1.



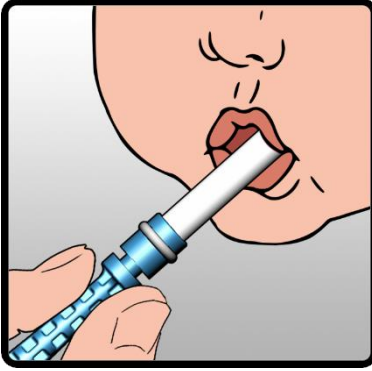
In preparation for collection, place contents on a clean and dry surface.

2.



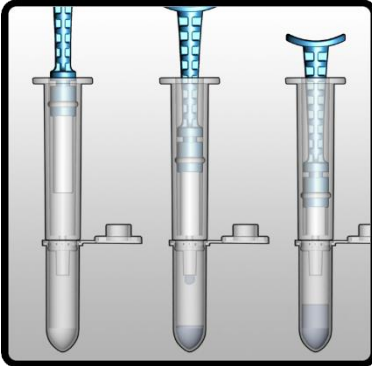
Attach the Eppendorf tube provided to the base of the Plastic Compression Tube firmly.

3.



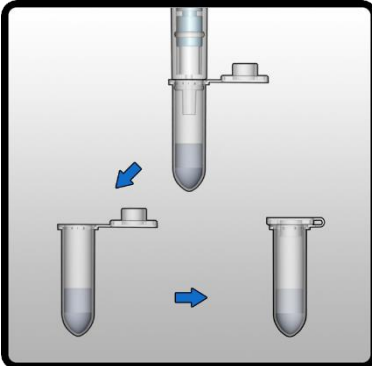
Place the tip end of the white absorbent collection pad of the Collector into the mouth of the infant where saliva pools, and collect until the pad is saturated.

4.



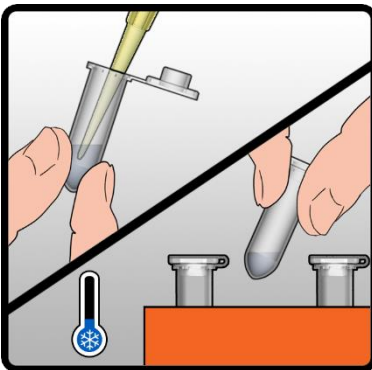
Place the white absorbent pad end into the Compression Tube, holding the Collector in an upright position, and firmly push the plunger downwards to transfer saliva from the absorbent pad into the Eppendorf Tube. Push and hold for 15 seconds.

5.



Gently remove the Eppendorf Tube from the end of the 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 COLLECTOR (WITH COMPRESSION TUBE)
EPDF-202	2.0 mL Eppendorf Tube
Note	The Micro•SAL™ kit 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 KIT COMPONENTS
3. Kits are for single use only. Used Collectors and samples should be treated as potentially infectious and disposed of in accordance with current regulations.
4. Do not use kits beyond the expiration date printed on the pouch.
5. Prior to use, record subject information on each of the 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 Kits are provided in clean, 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™ Collector by 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 Kit does not diagnose any disease.

Ordering Information

Micro•SAL™ Infant Saliva Collection Kits are sold in units of 15 kits per box and 10 boxes (150 kits) per shipping box (see Ordering Information below).

Micro•SAL™ Infant Saliva Collection Kit

Catalog Number: MRSAL-402

Quantity: 15/150

0.5 mL Eppendorf Tubes

Catalog Number: EPDF-202

Quantity: 50/500

Optional Component

Tube Rack

Catalog Number TRAC-001

Quantity: 1

Final Note

Micro•SAL™ Infant Saliva Collection Kits are available in different custom formats depending upon the required application. Please contact Oasis Diagnostics® Corporation 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: 20170510

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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