

Instructions for Use

REF CE-21001-048

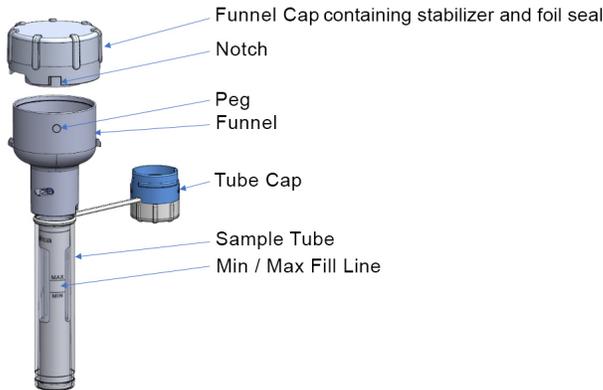
INTENDED USE

SalivaGard HT DNA is intended for the collection and preservation of human saliva DNA for use in In Vitro Diagnostic applications. This product is FOR EXPORT ONLY. It is not to be sold in the United States.

SUMMARY AND PRINCIPLES

SalivaGard HT DNA is designed for efficient self-collection, preservation, shipping, storage, and automated processing of human saliva samples for DNA purification and analysis. Saliva DNA samples collected using SalivaGard HT DNA are stable at room temperature (15°C to 30°C) for up to 12 months, and yield high quality DNA using a wide selection of commercial DNA purification kits.

KIT CONTENTS



WARNINGS AND PRECAUTIONS

1. For In Vitro Diagnostic Use.
2. Do not use if packaging is damaged or foil seal in funnel cap is broken or leaking.
3. Do not use beyond expiration date.
4. Avoid skin contact with SalivaGard HT DNA reagent.
5. Do not ingest SalivaGard HT DNA reagent.
6. Choking Hazard: Tube Cap is a potential choking hazard.

Contents of this reagent may cause skin and eye irritation.

1. In case of skin contact, immediately wash with soap and water and rinse thoroughly.
2. In case of eye contact, rinse immediately with plenty of water for at least 15 minutes and seek medical advice.
3. If accidental swallowing occurs, immediately seek medical advice.
4. Refer to SDS in case of accidental ingestion or skin contact. All SDS information is available at http://biomatrica.com/support_sds.php.

STORAGE AND STABILITY

Pre-Collection:

1. Store SalivaGard HT DNA kits at room temperature (15°C to 30°C) until the end of shelf life marked by the expiration date.
2. Avoid direct exposure to sunlight.

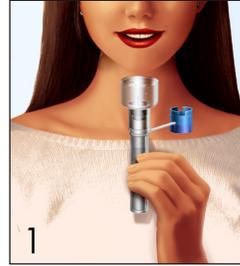
Post-Collection:

1. Store SalivaGard HT DNA sample tubes at room temperature for up to 12 months.

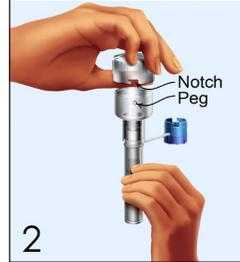
COLLECTION PRECAUTIONS

1. Do NOT eat, drink, smoke, or chew gum 30 minutes prior to providing saliva sample or results may be affected.
2. Do not remove the foil seal from the funnel cap.
3. If liquid does not dispense after twisting the funnel cap, press and twist further. If liquid still does not dispense, discard the intact device.
4. Do not remove the funnel cap.

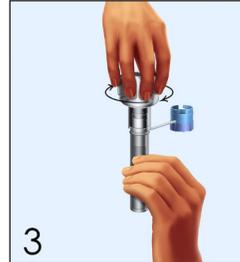
DONOR COLLECTION INSTRUCTIONS



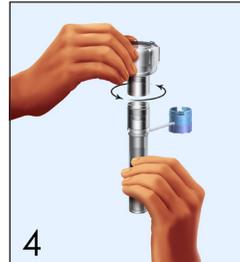
1. Hold Sample Tube upright. Spit into Funnel until saliva level (excluding bubbles/foam) is between the MIN and MAX fill lines marked on the Sample Tube. If saliva flow from Funnel to Sample Tube is slow, tap bottom of tube against a hard, level surface.



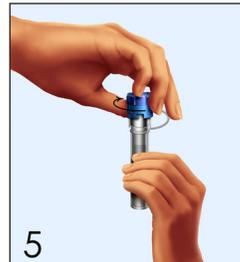
2. Place the Funnel Cap on the Funnel by aligning the Notch with the Peg. Press down firmly on the Funnel Cap to break foil seal.



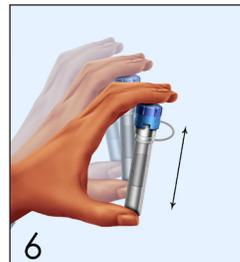
3. Twist slowly and firmly clockwise until Funnel Cap locks (clicking sound). Wait 10 seconds to ensure that all of the stabilizing solution has flowed into the Sample Tube. If flow from Funnel Cap to Sample Tube is slow, tap bottom of Sample Tube against a hard level surface.



4. Unscrew and discard the Funnel and Funnel Cap together as one piece.



5. Screw the Tube Cap securely onto the Sample Tube.



6. Shake Sample Tube for 5 seconds.

Biomatrica, Inc.
5627 Oberlin Drive, Suite 120
San Diego, CA 92121, USA

EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Ordering Information:
Web: www.biomatrica.com
Email: orders@biomatrica.com
Phone: 00 1 858 550 0308

Doc # 130061CE Rev C - 20170718

Glossary of Harmonized Symbols			
IVD In Vitro Device	15°C to 30°C Temperature Limitation	Use By	
REF Catalog Number	Do Not Re-Use	EC REF Authorized Representative	
LOT Batch Code	Keep Away From Sunlight	CE CE Marking	
Consult Instructions			

SalivaGard *HT* DNA IFU Directions

Instructions for use can be obtained via the internet at <http://biomatrica.com/salivagard-ht-dna.php>, by calling the following phone number: 00 1 858 550 0308, or by calling your local supplier.