



SalivaGard™ HT DNA

User Manual

REF CE-21001-048

CE **IVD**

For In Vitro Diagnostic Use.

Biomātrica®



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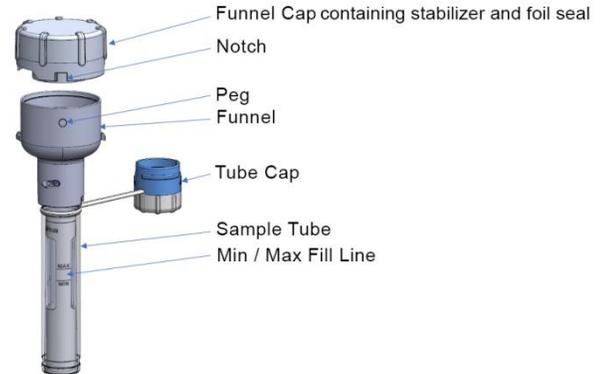
SalivaGard HT DNA Product and Ordering Information

Description	Quantity	Catalogue Number
SalivaGard HT DNA	48 kits	CE-21001-048

Orders may be placed online at www.biomatrica.com, via email at orders@biomatrica.com or via phone at 00 1 858 550 0308.

SalivaGard HT DNA Kit Contents

SalivaGard HT DNA (48 kits) Catalogue No. CE-21001-048	
Item	Quantity
SalivaGard HT DNA IFU	One (1) per kit
Funnel Cap with foil seal	One (1) per kit
Collection Device Assembly Funnel Tube Cap Sample Tube	One (1) per kit



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 the 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.
7. Dispose of all specimens, reagents and other potentially contaminated materials in accordance with local, state and federal regulations.

Note: Contents of this kit may cause skin and eye irritation.

1. In case of skin contact, immediately wash with water and soap 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 Conditions

Pre-Collection

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

Post-Collection

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

Intended Use

SalivaGard *HT* DNA is intended for the collection and preservation of human saliva DNA for use in In Vitro Diagnostic applications.

Introduction

Summary and Principle

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.

Sample Collection and Preservation Features

- Integrated stabilizer in the funnel cap and a liquid retention seal minimizes donor exposure to chemicals and contamination. The integrated stabilizer is optimized to immediately preserve DNA after saliva collection.
- Pierceable tube cap eliminates the need to uncap the device prior to laboratory processing of samples for more efficient processing in automated systems.
- Laser-etched, triple redundant identification markers (1D, 2D, and alphanumeric barcoded labels) on the ID sleeve support automated processing and sample tracking.

Specimen Collection Procedure

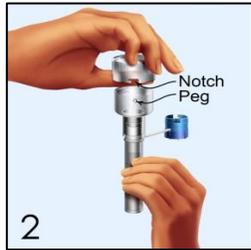
Important Notes Before Starting:

1. Do NOT eat, drink, smoke, or chew gum 30 minutes prior to providing saliva sample.
2. Do NOT remove the foil seal from the funnel cap.
3. If liquid from the Funnel Cap does not dispense, do-not remove the funnel cap. Dispose the device, all materials, and other potentially contaminated materials in accordance with local, state and federal regulations.

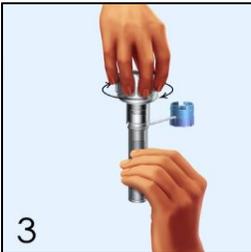
Procedure for Sample Collection



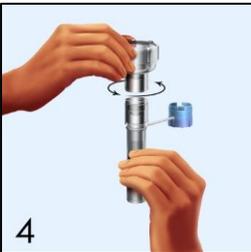
1. Hold Sample Tube upright. Spit into Funnel until saliva level (excluding bubbles/foam) is between the MIN and MAX fill lines marked on the Sample Tube. If saliva flow from Funnel to Sample Tube is slow, tap bottom of tube against a hard, level surface.



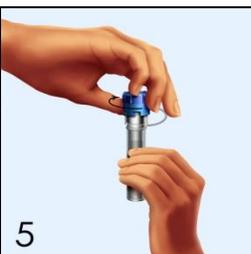
2. Place the Funnel Cap on the Funnel by aligning the Notch with the Peg. Press down firmly on the Funnel Cap to break foil seal.



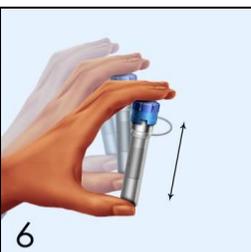
3. Twist slowly and firmly clockwise until Funnel Cap locks (clicking sound). Wait 10 seconds to ensure that all of the stabilizing solution has flowed into the Sample Tube. If flow from Funnel Cap to Sample Tube is slow, tap bottom of Sample Tube against a hard level surface.



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 the Sample Tube for 5 seconds.

Sample Processing

DNA from saliva stored in SalivaGard *HT* DNA tubes can be purified using commercially available kits. Recommended DNA purification methods can be found in Appendix A.

Automated Sample Processing

When using SalivaGard *HT* DNA tubes with an automated liquid handling instrument, refer to the manufacturer's instructions for proper instrument use. Contact the manufacturer for accessories such as racks and lock down modules.

Materials and Equipment Required but Not Provided for Automated Processing
<ul style="list-style-type: none">• Sterile, aerosol-barrier pierceable pipette tips (for automated systems)
<ul style="list-style-type: none">• Vortex mixer (if vortex feature is not present on automated system)*

Manual Sample Processing

Materials and Equipment Required but Not Provided for Manual Processing
<ul style="list-style-type: none">• Sterile, aerosol-barrier pipette tips
<ul style="list-style-type: none">• Vortex mixer*

*Ensure that instruments have been checked, maintained, and calibrated regularly according to the manufacturer's recommendations.

The following guidelines are suggested for the manual processing of saliva samples collected in SalivaGard *HT* DNA.

1. Mix sample by briefly vortexing for 3-5 seconds.
2. Unscrew the tube cap from the sample tube.
3. Remove the blue liquid retention seal from the sample tube by gently prying it out of the sample tube using a disposable pipette tip or similar object.
4. Pipette the sample from the sample tube.

Product Use Limitations

1. Improper collection may affect DNA yield and quality. See Troubleshooting Guide for details.
2. SalivaGard *HT* DNA is intended for the collection and stabilization of human DNA from saliva. It is NOT intended for the collection and stabilization of RNA, proteins or hormones.
3. Single use collection device only.

Troubleshooting Guide

The following troubleshooting guide includes suggestions for addressing commonly occurring situations. Biomatrixa's Technical Support scientists are available to answer questions about the information and protocols in this user manual (see pg. 10 for contact information or visit www.biomatrixa.com).

Situation	Comment	Reason/Suggestion
There is a significant quantity of precipitate in the sample after storage or shipment.	SalivaGard <i>HT</i> DNA formulation lyses cells and denatures proteins, which will precipitate over time. Precipitation does not affect the DNA stabilization properties of the formulation nor the yields.	Ensure that sample is mixed before DNA purification by inverting the sealed tube 3-5 times or by vortexing it for 3-5 seconds.
Low DNA yield	Possible reasons: <ul style="list-style-type: none"> - Low number of nucleated cells in the saliva sample. - Donor provided less than 1.8 mL or more than 2.1 mL of saliva sample. - Donor provided saliva sample immediately after eating/drinking/chewing gum. - SalivaGard <i>HT</i> DNA sample not mixed thoroughly prior to DNA purification. - Choice of purification kit/chemistry. 	<ul style="list-style-type: none"> - Cell numbers can vary 10-fold between donors resulting in wide range of DNA yield. - Ensure donor follows the instructions in the IFU. - Ensure donor follows the instructions in the IFU. - Invert the SalivaGard <i>HT</i> DNA tube 3-5 times immediately prior to DNA isolation or vortex it for 3-5 seconds. - DNA purification from SalivaGard <i>HT</i> DNA samples has been tested successfully on multiple commercial purification kits; however, we do not guarantee the yields and quality of DNA purified using alternative methods not listed in this manual.
Isolated DNA is impure	Possible reasons: <ul style="list-style-type: none"> - Choice of purification kit/chemistry. 	DNA purification from SalivaGard <i>HT</i> DNA samples has been tested successfully on multiple commercial purification kits; however, we do not guarantee the yields and quality of DNA purified using alternative methods not listed in this manual.

Appendix A: DNA Purification from SalivaGard *HT* DNA Tubes

Saliva samples stabilized using SalivaGard *HT* DNA are compatible with multiple commercial purification chemistries using both automated and manual methods. Biomatrica has tested several chemistries to ensure compatibility and the table below provides chemistry- and instrument-specific recommendations based on internal testing.

Purification Chemistry	Purification Instrument	Recommended Sample Volume	Additional Recommendations
Qiagen QIAasymphony [®] DSP DNA Midi Kit	Qiagen QIAasymphony [®]	350 µL	<ul style="list-style-type: none">• Use QIAasymphony SP protocol Blood 350
Macherey-Nagel NucleoMag [®] Blood 200 µL Kit	Thermo Fisher KingFisher [™]	200 µL	<ul style="list-style-type: none">• Use as directed for blood in manual
QIAamp [®] Mini Blood	Manual	200 µL	<ul style="list-style-type: none">• Use as directed for blood in manual

Appendix B : DNA Quantification Recommendations

Fluorescence Method

Compared to traditional methods using absorbance at 260 nm, assays that use fluorescent dyes can precisely detect double-stranded DNA (dsDNA) in the presence of single-stranded DNA (ssDNA), RNA, and free nucleotides. Biomatrica recommends using the fluorescent dyes in commercially available kits such as the Thermo Fisher's Quant-iT™ PicoGreen dsDNA Assay Kit (Cat. No. P7589) to quantify dsDNA purified from saliva collected in SalivaGard *HT* DNA.

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Technical Assistance

Biomatrica, Inc. is committed to providing outstanding technical support. Biomatrica's Technical Service Department is staffed by experienced scientists with hands-on experience in molecular biology and the use of Biomatrica's products. Please contact Biomatrica directly with any questions regarding the SalivaGard *HT* DNA kit.

Technical Service Department

Phone (USA): 00 1 858 550 0308
 Web: www.biomatrica.com
 Email: techsupport@biomatrica.com

Glossary of Harmonized Symbols

 In Vitro Device	 Catalogue Number	 Batch Code	 Hazard	 Use By	 Authorized Representative in the European Community
 Keep Away From Sunlight	 Manufacturer	 Consult Instructions For Use	 Temperature Limitation	 Do Not Re-use	 CE Marking
Glossary of symbols may contain symbols not used in the labeling of this product					

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