



SalivaGard™ DNA

User Manual

REF 21008-048A

For Research Use Only. Not for use in diagnostic procedures.

Biomātrica®



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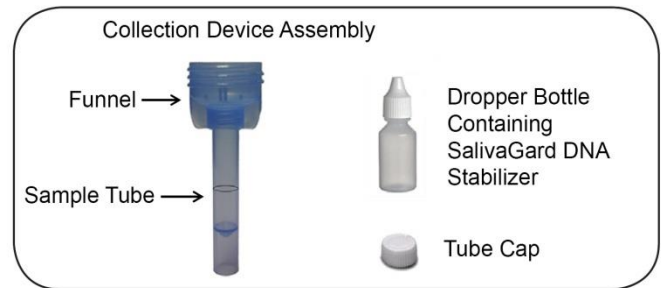
SalivaGard DNA Product and Ordering Information

Description	Quantity	Catalogue Number
SalivaGard DNA	48 packs	21008-048A

Orders may be placed online at www.biomatrica.com, via email at orders@biomatrica.com or via phone at 1-866-379-6879 (Toll-free in the US and Canada) or 1-858-550-0308.

SalivaGard DNA Pack Contents

SalivaGard DNA (48 packs) Catalogue No. 21008-048A	
Item	Quantity
SalivaGard DNA IFU	One (1) per pack
Collection Device Assembly Funnel Tube Cap Sample Tube	One (1) per pack
Dropper Bottle Containing SalivaGard DNA	One (1) per pack



Warnings and Precautions

1. For Research Use Only. Not for use in diagnostic procedures.
2. Do NOT use if packaging is damaged.
3. Do NOT use beyond the expiration date.
4. Avoid skin contact with SalivaGard DNA reagent.
5. Do NOT ingest SalivaGard 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 pack 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 DNA packs 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 DNA sample tubes at room temperature for up to 12 months.

Intended Use

SalivaGard DNA is intended for the collection and preservation of human saliva DNA. For Research Use Only. Not for use in diagnostic procedures.

Introduction

Summary and Principle

SalivaGard DNA is designed for efficient self-collection, preservation, shipping, and storage of human saliva samples for DNA purification and analysis. Saliva DNA samples collected using SalivaGard 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

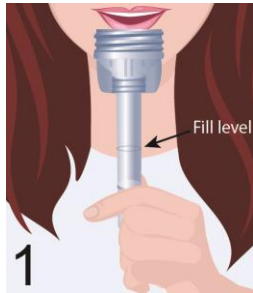
- Reliable and cost-effective saliva collection
- Simple, User-friendly collection protocol
- Compatible with manual and automated purification systems
- Optimal for a wide range of downstream applications

Specimen Collection Procedure

Important Notes Before Starting:

1. Do NOT eat, drink, smoke, or chew gum 30 minutes prior to providing saliva sample.

Procedure for Sample Collection



1. Hold Sample Tube upright. Spit into the Funnel until saliva level (excluding bubbles/foam) has reached the “fill” level marked on the Sample Tube. This may take a few minutes.



2. Remove cap from the Dropper Bottle and squeeze to empty the contents into the Saliva Collection Device.



3. Unscrew the Funnel from the Sample Tube and discard. Be careful not to spill any of the liquid.



4. Screw the Tube Cap onto the Sample Tube until it is tightly sealed.



5. Mix gently by inverting the Sample Tube 5 to 7 times. The saliva mixture is now ready to ship or store.

Sample Processing

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

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 DNA.

1. Mix sample by briefly vortexing for 3-5 seconds.
2. Unscrew the tube cap from the sample tube.
3. 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 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.
4. For Research Use Only. Not for use in diagnostic procedures.

Troubleshooting Guide

The following troubleshooting guide includes suggestions for addressing commonly occurring situations. Biomatrix's Technical Support scientists are available to answer questions about the information and protocols in this user manual (see pg. 12 for contact information or visit www.biomatrix.com).

Situation	Comment	Reason/Suggestion
There is a significant quantity of precipitate in the sample after storage or shipment.	SalivaGard 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	<p>Possible reasons:</p> <ul style="list-style-type: none"> - Low number of nucleated cells in the saliva sample. - Donor provided less than the recommended fill volume of saliva sample. - Donor provided saliva sample immediately after eating/drinking/chewing gum. - SalivaGard 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 DNA tube 3-5 times immediately prior to DNA isolation or vortex it for 3-5 seconds. - DNA purification from SalivaGard 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	<p>Possible reasons:</p> <ul style="list-style-type: none"> - Choice of purification kit/chemistry. 	DNA purification from SalivaGard 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 DNA Tubes

Saliva samples stabilized using SalivaGard DNA are compatible with multiple commercial purification chemistries using both automated and manual methods. Biomatrix 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
Puregene [®]	Manual	1000 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 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 DNA product.


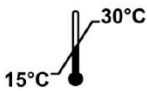






Technical Service Department

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Glossary of Harmonized Symbols

	Catalog Number		Temperature Limitation
	Batch Code		Do Not Reuse
	Consult Instructions		Keep Out of Sunlight
	Manufacturer		Use By

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