

MapQuant Dx™ Path Kit

For collection of tissue sample & RNA preservation
during storage and transport



Instructions for Use
Version 01, July 2008

REF

MAPK-01-CE

IVD

CE



+15°C +25°C

MapQuant Dx™ Path Kit

For collection of tissue sample & RNA preservation
during storage and transport

For in Vitro Diagnostic use

Introduction	3
Context	3
Indications on use and Performance	3
Content of this kit	3
Storage	3
Quality Control	3
Stability	3
Equipment to be supplied by User	4
Safety information	4
Importantes notes	4
Procedure	5
1. Fresh sample collection	5
2. Frozen sample collection	6
3. Sample shipment to the Laboratory	7
Contact information	8
Notice to the purchaser	8

Introduction

Context

Sample collection procedures, transport and storage conditions are crucial to analyze gene expression levels in a sample. RNA are very labile and degradation can occur immediately after tissue resection. It is therefore very important to prevent RNA degradation by stabilizing RNA as quickly as possible after tissue harvesting, and to avoid further degradation by storing and shipping the sample at adequate temperature conditions.

Preservative solution in the kit preserves RNA 1 day at 37°C and 7 days at +15 / +25°C or 3 weeks at 4°C. A temperature indicator ensures that the sample has not been exposed to temperatures that degrade its RNA.

Indications on use and Performance

Kit for tissue collection and RNA preservation during storage and transport.

Preservative solution in the kit preserves RNA 1 day at 37°C and 7 days at +15 / +25°C or 3 weeks at 4°C.

Kit content

MapQuant Dx™ Path Kit	Catalog no.	MAPK-01-CE
• Outer plastic box		1
• Instruction for Use (IFU)		1
• Tube containing 1.5 ml of preservative solution		1
• Disposable scalpel		1
• 95kPa IATA compliant pouch		1
• Absorbent		1
• Histological slide mailer box		1
• Labels with the unique sample's identifier (Ipsogen Id)		2
• Sample Report Form (SRF)		1
• Temperature indicator		1
• Security seal label		1

Storage

The MapQuant Dx™ Path Kit should be stored dry at room temperature (+15 to +25°C).

Quality Control

The kit is manufactured in an ISO13485: 2003 certified laboratory, which guarantees standard stages of manufacture, validation and documentation compliant with Good Manufacturing Practices. The certificates of analysis are available upon request at the following address: support@ipsogen.com.

Stability

Under correct storage conditions, the kit will remain stable until the expiration date mentioned on the back of the box. These storage conditions and the expiration date apply to both opened and un-opened components.

Equipment to be supplied by the User

1. Disposable gloves to prevent RNA degradation by RNases present on the hands
2. If possible, paper towel or aluminium to cover surfaces while manipulating tissue samples

Safety information

The material safety data sheet of the RNA preservative solution is available on request.

Handle the sample with care when cutting it with sharp tools.

The human tissue must be handled as if they were potentially infectious and should be removed with special precautions, in agreement with the EU-OSHA - the European Agency for Safety and Health at Work.

Never pipette the reagents by mouth and avoid contact with skin and mucous membranes. If reagent is exposed to sensitive areas, wash thoroughly with water and contact a physician.

Important notes

The reagents and instructions supplied in this kit have been validated for optimal performance. Procedure deviation may impact on RNA integrity and may invalidate the assay results. We therefore recommend the following:

- Before starting, you must verify that the kit is still valid (check the expiry date indicated at the back of the box and on the tube).
- Use the disposable scalpel supplied in the kit to collect the sample, or use any other single-use device.
- After harvesting, the sample should be immediately placed in the dedicated tube so that the reagent covers the entire sample.
- Time between tissue resection and sample handling should be reduced at the minimum (ideally 15 minutes, max 1 hour), in order to prevent gene expression changes and RNA degradation.
- This kit can be used for fresh or frozen tissue only, but not for fixed tissue. See sampling procedure below.
- This kit is for single use only. Do not reuse.
- Do not dilute or substitute tissue collection solution with any other solution as it may result in a loss of preserving capacity and the product may chemically react dangerously with some agents.

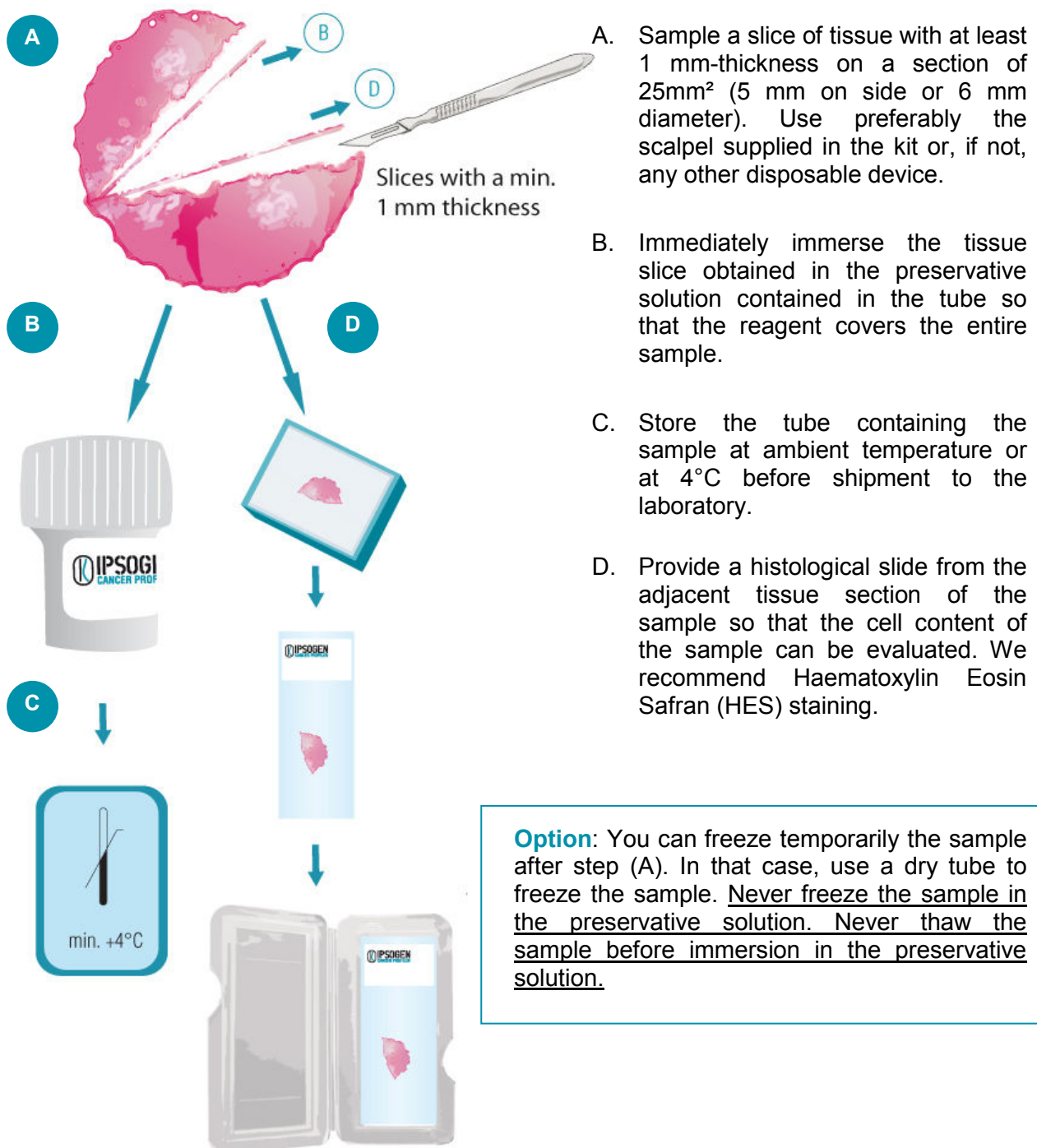
Sampling and shipping procedure



- **Verify that the kit is still valid** (check the expiry date indicated on the back of the box).
- **Wear gloves throughout the procedure when manipulating tissues.**
- **Fresh and frozen samples should at least weight 25mg and must be representative of the tissue to be analyzed.**

1. Fresh sample collection

The sample must be taken on surgically resected tissue within one hour.



2. Frozen sample collection

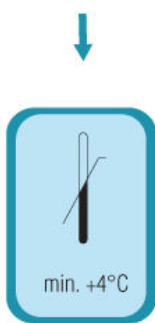
Sample should at least weight 25mg and must be representative of the tissue to analyzed.

I



- I. Immediately immerse the sample in the preservative solution contained in the tube so that the reagent covers the entire sample. Never thaw the sample before its immersion in the preservative solution.

II



- II. Store the tube containing the sample at ambient temperature or at 4°C before shipment to the laboratory.

Caution: Do not subtract or add any solution to the tube. Ensure that the cap of the tube is securely fastened. If dealing with several samples, make sure that the label on the form is identical to the one on the tube.

The tube containing the sample should be sent within the 3 days to the laboratory.

3. Sample shipment to the Laboratory

Once collected, the sample should be immediately immersed in the solution for the preservation and the RNA stabilization contained in the tube.

The tube containing the sample should be sent within the 3 days to the laboratory.



- A. Put the tube within the 95kPa IATA compliant pouch, supplied with the kit.
- B. Securely close the bag following the instructions indicated on it.
- C. Place the histological slide in the dedicated mailer box supplied.



- D. Complete the Sample Report Form (SRF).



- E. Activate the temperature indicator by pulling the plastic protective film. From that point until delivery, the temperature indicator will monitor any temperatures over 37°C.



- F. Fold the bag and place it in the outer plastic box with the histological slide mailer box and the SRF.



- G. Close the box with the security seal label (supplied).



- H. Ship the box as soon as possible at room temperature to DNAVision SA (25, avenue Georges Lemaitre B-6041 Gosselies-Charleroi, Belgium).

Tel: + 32 71 37 85 27 / Fax: + 32 71 37 85 01).

Contact: Jean-François Laes (Head of the microarray unit)

CAUTION: Ship at ambient temperature.

Do not freeze sample or use dry ice for shipment.

Contact information

For information regarding sample logistics, please contact DNAVision:

DNAVision SA

Avenue Georges Lemaître 25
B-6041 Gosselies-Charleroi
Belgique
Tel: +32 71 37 85 27
Fax: +32 71 37 85 01
Email: info@dnavision.be
Web: www.dnavision.be

For medical or commercial information, please contact IPSOGEN:

Ipsogen SA

Global Headquarters
Luminy Biotech Entreprises
Case 923, 163, avenue de Luminy
13288 MARSEILLE cedex 9
France
Tel: +33 (0)4 91 29 30 90
Fax: +33 (0)4 91 29 30 99
Email: support@ipsogen.com
Web: www.ipsogen.com

Notice to the purchaser

Information in this document is subject to change without notice. IPSOGEN assumes no responsibility for any errors that may appear in this document. This document is believed to be complete and accurate at the time of publication. In no event shall IPSOGEN be liable for incidental, special, multiple, or consequential damages in connection with, or arising from the use of this document. MapQuant Dx is a trademark of ipsogen SA.



For In Vitro Diagnostic use
MAPK-01-CE (03/07/2008)
© Copyright 2008, IPSOGEN SA. All rights reserved.