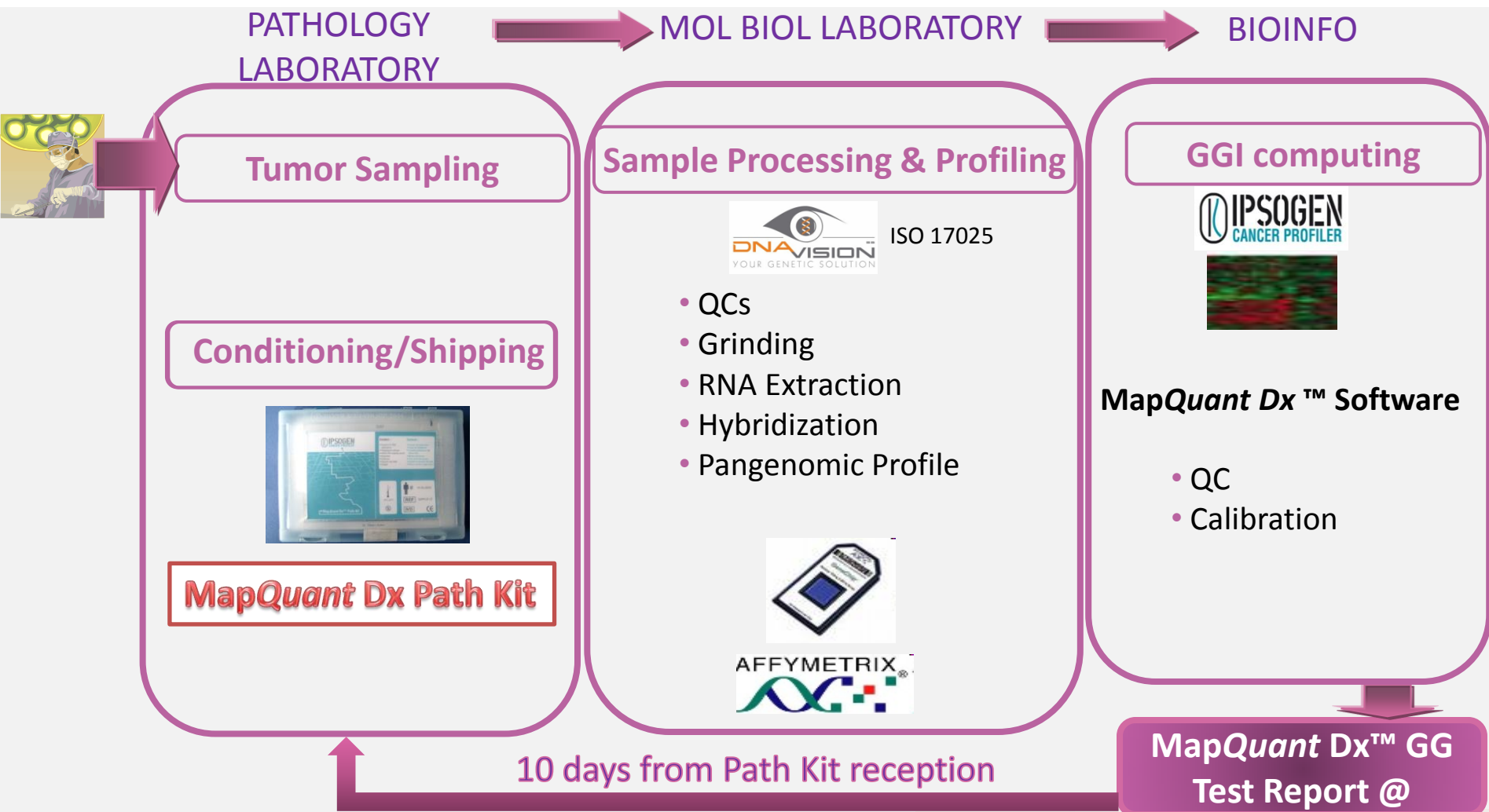


GGI MapQuant Dx™ Process

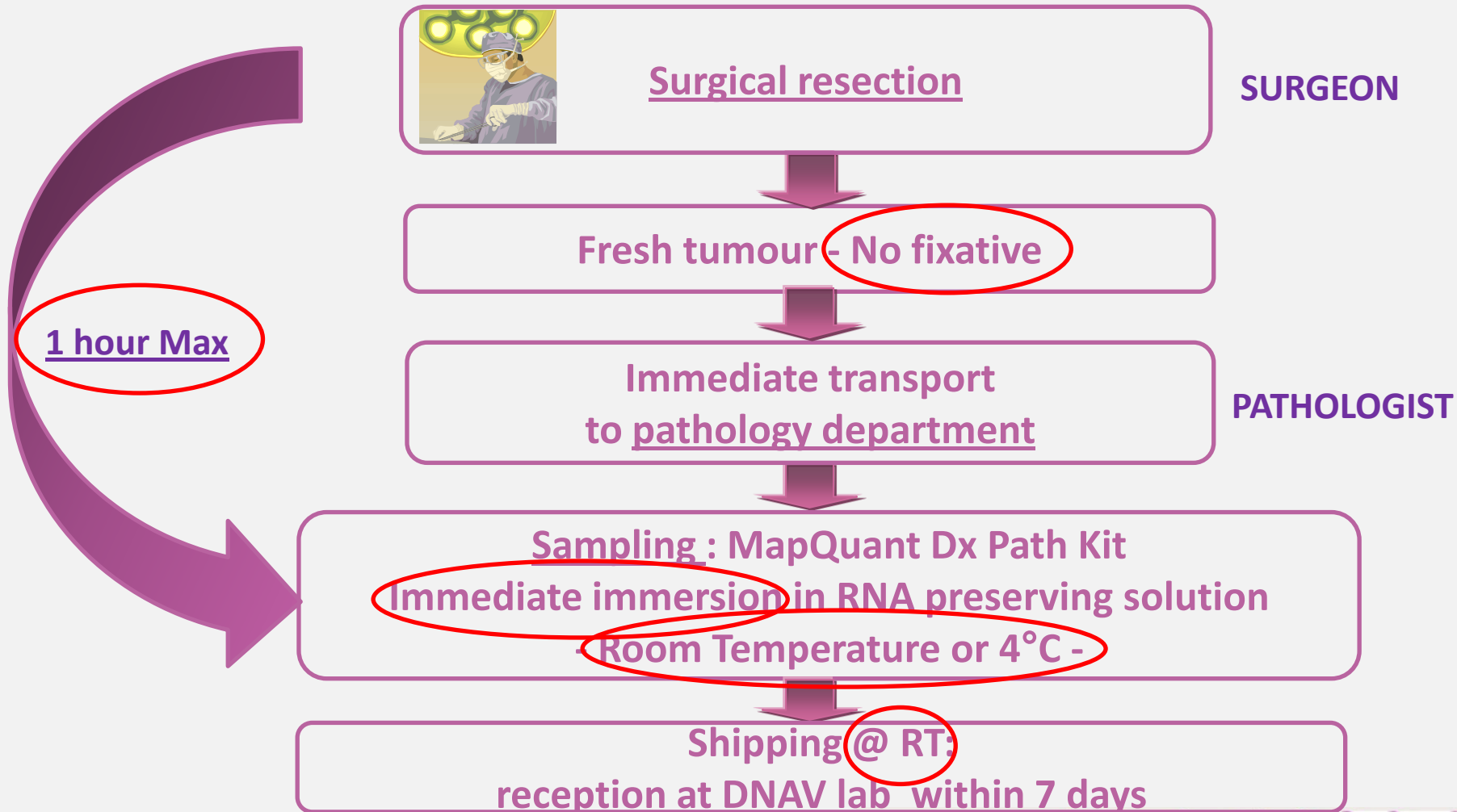
Feasibility Study
IJB, Brussels 26/10/2009.

MapQuant Dx™ Process

A 3-step process



Tumour Sampling Process



Tumour Sampling from fresh tissue and Storage

MapQuant Dx™ Path Kit: tissue sample collection & RNA preservation during storage and transport

PATHOLOGY LABORATORY

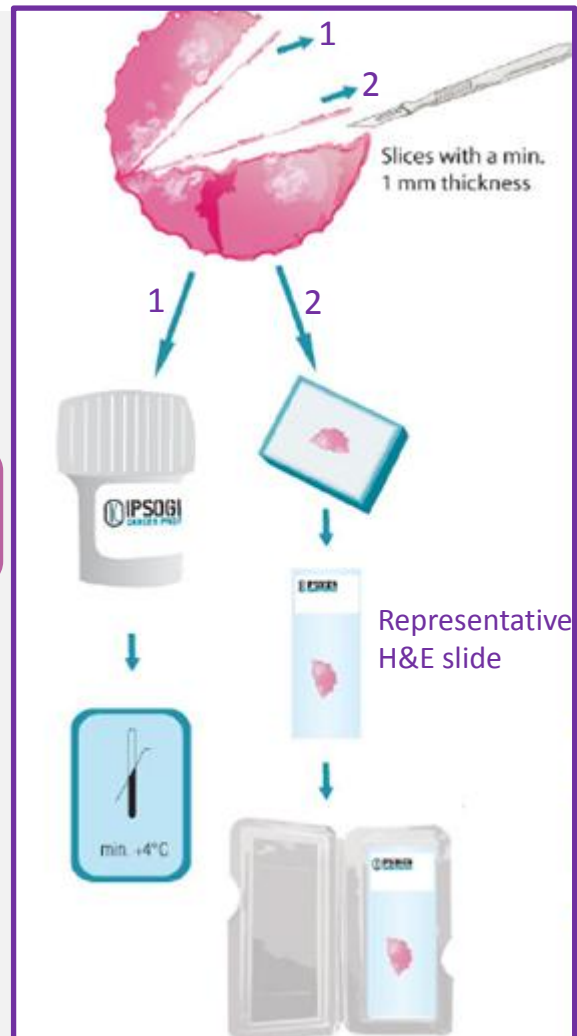
Sampling

- Surgical biopsy
- representative sample
- Ø 3 mm min.
- **Fresh**

Immediate immersion in
preservative solution
(**1 hour max** after resection)

Storage

- **never freeze**
- **+4°C or RT**



Tumour Sampling from frozen tissue and Storage

MapQuant Dx™ Path Kit: tissue sample collection & RNA preservation during storage and transport

Nerver defrost

Frozen tissue



200µm (20µm microtome slices x10)

Immediate immersion in
preservative solution
(1 hour max after resection)

Storage

- never freeze
- +4°C or RT




MapQuant Dx Path Kit preparation for shipping

SRF

Path Kit

Shipping ASAP

	SRF Sample Report Form / Fiche de suivi de l'échantillon	FQP01-02 V02
	PK-09-XXXXX	Effective as of/au 14/04/2009

Section 1_Pathology laboratory information / Information sur le laboratoire de pathologie

1. Institution Name / Nom de l'institution:
2. Address / Adresse:
3. Service / Laboratoire:
4. Pathologist details / Coordonnées de l'Anatomopathologiste:
 - a. Name / Nom:
 - b. Position / Fonction:
 - c. Phone number / Téléphone:
 - d. Fax number / Fax:
 - e. E-mail address / Adresse email:

Section 2_Sample description / Description de l'échantillon

1. Sample Id / Identifiant de l'échantillon:
2. Date of sampling / Date de collecte: ____/____/____
3. Sampling protocol / Protocole de collecte: ☐ As recommended / Comme recommandé (cf. IFU/ notice)
☐ Other / Autre:
4. Time between tumor resection and sampling / Délai entre la résection de la tumeur et la collecte de l'échantillon (HH/MM): ____/____
5. Sample / Echantillon: ☐ Fresh tissue / Tissu frais ☐ Frozen tissue / Tissu congelé
6. Histological grade / Grade histologique: ☐ Grade 1 ☐ Grade 2 ☐ Grade 3
7. Percentage of tumor cell / Cellularité tumorale > 30%: ☐ Yes / Oui ☐ No / Non ☐ ND
8. Storage conditions in the preservative solution before shipment / Conditions de stockage dans la solution de préservation avant transport:
 ☐ Room temperature / Température ambiante (HH/MM) ☐ +4°C. Duration (HH/MM): ____/____

Section 3_Sample Shipment / Expédition de l'échantillon

(Should be done within three days post storage in preservative solution / Doit être réalisé dans les trois jours après stockage dans la solution de préservation)

1. Date of shipment / Date de l'expédition: ____/____/____

2. Checks / Contrôles:

- a. Temperature tag was activated / La sonde de température a été activée ☐
- b. Id reported on tube, slide, SRF and box are identical / Les identifiants reportés sur le tube, la lame, la fiche de suivi et la boîte sont les mêmes ☐
- c. HE/S control slide included / Lame contrôle HE/S incluse ☐

Once completed, place this form, slide mailer and bag containing tube & absorbent in the outer blue box. Close the box and seal it with the security seal label.

Placer ce formulaire rempli ainsi que le porte-lame et le sachet contenant le tube & la matière absorbante dans la boîte bleue. Fermer la boîte puis sceller avec l'étiquette de sécurité.

Je déclare avoir pris connaissance et avoir compris les conditions générales d'utilisation du test MapQuant Dx™ Genomic Grade / I acknowledge that I have read and understood the general conditions of use of the MapQuant Dx™ Genomic Grade (www.ipsogen.com)

date and signature



- Specimen in RNA preservative solution
- H&E slide


- SRF

- Temperature probe

- IATA 650 compliant packaging



+15°C to +25°C
(NO DRY ICE)

	SRF	FQP01-02 V02
	Sample Report Form / Fiche de suivi de l'échantillon	Effective as of/au 14/04/2009

Section 1_Pathology laboratory information / Information sur le laboratoire de pathologie

1. Institution Name / Nom de l'Institution:
2. Address / Adresse:
3. Service / Laboratoire:
4. Pathologist details / Coordonnées de l'Anatomopathologiste:
 - a. Name / Nom:
 - b. Position / Fonction:
 - c. Phone number / Téléphone:
 - d. Fax number / Fax:
 - e. E-mail address / Adresse email:

Section 2_Sample description / Description de l'échantillon

1. Sample Id / Identifiant de l'échantillon:
2. Date of sampling / Date de collecte: ____/____/____
3. Sampling protocol / Protocole de collecte: ☐ As recommended / Comme recommandé (cf. IFU/ notice)
☐ Other / Autre:
4. Time between tumor resection and sampling / Délai entre la résection de la tumeur et la collecte de l'échantillon (HH/MM): __/__
5. Sample / Echantillon: ☐ Fresh tissue / Tissu frais ☐ Frozen tissue / Tissu congelé
6. Histological grade / Grade histologique : ☐ Grade 1 ☐ Grade 2 ☐ Grade 3
7. Percentage of tumor cell / Cellularité tumorale > 30%: ☐ Yes / Oui ☐ No / Non ☐ ND
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☐ Room temperature / Température ambiante (HH/MM) ☐ +4°C Duration (HH/MM): __/__

Section 3_Sample Shipment / Expédition de l'échantillon

(Should be done within three days post storage in preservative solution / Doit être réalisé dans les trois jours après stockage dans la solution de préservation)

1. Date of shipment / Date de l'expédition: []/[]/[]

2. Checks / Contrôles :

- a. Temperature tag was activated / La sonde de température a été activée ☐
- b. Id reported on tube, slide, SRF and box are identical / Les identifiants reportés sur le tube, la lame, la fiche de suivi et la boîte sont les mêmes ☐
- c. HE/S control slide included / lame contrôle HE/S incluse ☐

Once completed, place this form, slide mailer and bag containing tube & absorbent in the outer blue box. Close the box and seal it with the security seal label.


Placer ce formulaire rempli ainsi que le porte-lame et le sachet contenant le tube & la matière absorbante dans la boîte bleue. Fermer la boîte puis sceller avec l'étiquette de sécurité.

Je déclare avoir pris connaissance et avoir compris les conditions générales d'utilisation du test MapQuant Dx™ Genomic Grade / I acknowledged that I have read and understood the general conditions of use of the MapQuant Dx™ Genomic Grade (www.ipsogen.com)

_____ date and signature

MapQuant Dx Genomic Grade Test Report

- Test report sent by e-mail and FAX:



MapQuant Dx™
Support +33(0)491 293090

GENOMIC GRADE REPORT

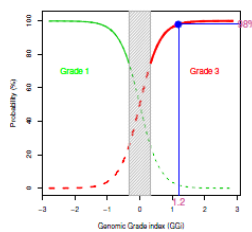
Institution (Prescriber):	Contact person:
Address:	Position:
Service:	Phone:
Specimen (Prescriber):	Fax:
	Email:
	Specimen ID (Ipsogen): PK-06-26153

TEST DESCRIPTION

MapQuant Dx™ Genomic Grade is an in vitro diagnostic test which quantifies the Genomic Grade index (GGi) from qualified Affymetrix GeneChip® microarray genomic profile obtained in an Ipsogen-certified partner laboratory. The expression levels of the 97 mRNAs which best discriminate grade 3 from grade 1 tumors are calibrated, averaged, and scaled using high-quality reference breast cancer profiles. Profiles are then classified as grade 1 or grade 3 according to their GGi value.

References:
1. Sotiriou et al. Gene expression profiling in breast cancer: understanding the molecular basis of histologic grade to improve prognosis. *J Natl Cancer Inst*. 2006; 98(4):262-72.
2. Liat et al. Definition of clinically distinct molecular subtypes in estrogen receptor positive breast cancer through genomic grade. *J Clin Oncol* 2007; 25(16):1233-45.

RESULT: GRADE ③



✓ The genomic grade index is 1.2; which corresponds to a grade of 3 (with a probability of 98 %)

QUALITY CONTROLS

RNA	passed	✓
Genomic Profile	passed	✓

Notes

Name: _____ Position: _____
Date and Signature

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MapQuant Dx™ is an in vitro diagnostic testing solution combining the use of MapQuant Dx™ Path XL™ (28-mers), with an ISO 15189:2013 certified lab. Service performed on Affymetrix® platform. Genomic indexes are computed through a Q&A compliant software. MapQuant Dx™ has been developed under the French lab Support Program of the French Health Products Safety Agency (ANSM). MapQuant Dx™ is a trademark of Ipsogen SA.

