DPD DEFICIDENCY TESTING – (5FU)

(Toxicity risk to fluoropyrimidines)
Using the multi-parametric approach 5FU ODPM TOX ™

Eurofins Biomnis Ireland, Tel: +353 1 295 8545 | Fax: +353 1 295 8550 | Email: sales@eurofins-biomnis.ie

- **The blood must be drawn before any chemotherapy or at least 1 week after the last course of treatment.**
- **Please note that 5FU must be requested only ONCE per patient.**

DOCUMENTS TO BE INCLUDED: Declaration of consultation and consent (see page 2)

1. PROFILE REQUESTED:

☑ EVALUATION OF THE RISK OF TOXICITY TO FLUOROPYRIMIDINES (Profile code 5FU)

2. REQUESTING CLINICIAN: (NB: if this information is given in the sticker below, there is no need to handwrite it here)

Organisation Name: _____

Clinician Name: _____ Clinician Phone. No.: _____

LABORATORY IDENTIFICATION **AND** PATIENT IDENTIFICATION STICKER(S) HERE

3. PATIENT DETAILS: (NB: if this information is given in the sticker below, there is no need to handwrite it here)

Gender: ☐ F ☐ M Date of birth: __ __ / __ __ / __ __ __ __

Surname: _____ First name(s): _____

Address: _____

City: _____ Country: **IRELAND**

4. CLINICAL DETAILS:

Patient Weight: _____ kg **Patient Height** _____ cm

Origin: ☐ Europe ☐ North Africa ☐ Asia ☐ Sub-Saharan Africa & West Indies ☐ Other: _____

Primary location of tumour: _____

Radiotherapy concomitant to chemotherapy: ☐ Yes ☐ No

Previous chemotherapy (for current illness): ☐ YES ☐ NO

IF YES: **Presence of toxicity:** ☐ YES ☐ NO

IF YES: **Grade of toxicity (1 to 5):** _____

Type of toxicity: ☐ Haematological ☐ Diarrhoea ☐ Mucitis ☐ HFS ☐ Coma

5. TREATMENT DETAILS:

Date of request: __ __ / __ __ / __ __ __ __

Scheduled date of chemotherapy: __ __ / __ __ / __ __ __ __

OR ☐ No chemotherapy prescribed yet

Chemotherapy protocol prescribed: _____

Duration of 5-FU infusion: ☐ 4h ☐ 2x23h ☐ 46h ☐ 96h ☐ 120h ☐ Other: _____ h

Or oral 5-FU prodrug: ☐ Capecitabine ☐ S1 ☐ Other: _____

Associated drugs (if any): ☐ Irinotecan ☐ Oxaliiplatin ☐ Cisplatin ☐ Bevacizumab ☐ Trastuzumab ☐ Panitumumab ☐ Carboplatin ☐ Cetuximab ☐ Other _____

6. PRE-ANALYTICAL INFORMATION - TO BE FILLED IN BY THE REQUESTING LABORATORY

Sample Date: __ __ / __ __ / __ __ __ __ **Time of Sampling** *hh:mm:* __ __: __ __

Time of freezing *(Lithium-heparin plasma) hh:mm*: __ __: __ __

Time of refrigeration *(Lithium-heparin whole blood) hh:mm*: __ __: __ __

MIXED TEMPERATURE

7. Comments / Observations:

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Declaration of consultation and consent
for testing of an individual's genetic characteristics

(In accordance with French Articles R.1131-5 and the Code of Public Health)

- **1 copy to be sent to the laboratory with the sample**
- **1 copy to be kept in the patient record**

DECLARATION OF MEDICAL CONSULTATION

Prior to the performance of examinations of an individual's genetic characteristics and his/her identification by DNA for medical purposes

I, the undersigned ..... **physician**,

In accordance with French Articles R.1131-4 and R. 1131-5 of the Code of Public Health,

- Certify to have interviewed the patient named below in a consultation on this date to provide him/her with information on investigated mutation characteristics, means for detecting such mutations and the options for prevention and treatment.

At .....,
on |_|_|/|_|_|/|_|_|

Signature and stamp of clinician

CONSENT FOR PERFORMING EXAMINATIONS OF AN INDIVIDUAL'S GENETIC CHARACTERISTICS

In accordance with French Articles R.1131-4 R.1131-5 and the Code of Public Health

I, the undersigned ..... born on |_|_|/|_|_|/|_|_|,

Residing at: .....

- Acknowledge that I have been informed by ..... on tests of genetic characteristics that will be performed in order to:
  - ☐ evaluate my genetic sensitivity to a drug treatment.
- To this end, I agree:
  - ☐ to a biological sample being obtained from me.
  - ☐ to a biological sample being obtained from my minor child or an adult under my guardianship.
- I am informed that the results of the examination of genetic characteristics will be presented to me by the above-named physician as part of an individual consultation. If examination reveals results other than those expected, the above-named clinician will determine what to do during an individual consultation.
- If part of the sample remains unused after examination,
  - ☐ I agree to its use, as appropriate, for scientific research purposes. In this case, all the medical data will be protected by total anonymisation. Consequently, I am aware that these scientific studies will neither benefit me nor put me at risk.

At .....,
on |_|_|/|_|_|/|_|_|

Signature of adult patient or legal guardian of the minor child or legal guardian of an adult under guardianship:

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SAMPLE PREPARATION
DPD DEFICIENCY TESTING (5FU)

IMPORTANT: Please note that in order to ensure the sample suitability for this test, you must follow the instructions for **step 1 and step 2 in order to provide samples for both Genotyping and Phenotyping.**

Samples MUST be drawn from peripheral sites only (not directly from the port-a-cath/implantable site or the infusion site).

5-FU ODPM TOX ™ — DPD DEFICIENCY TESTING - EVALUATION OF THE RISK OF TOXICITY TO FLUOROPYRIMIDINES BY A MULTI-PARAMETRIC APPROACH

The blood must be drawn before any chemotherapy or at least 1 week after the last course of treatment.

Step 1

5FUGE

Genotyping of *DPYD* gene* (and genotyping of *UGT1A1* if requested)

- Draw 1 x 4 ml Lithium Heparin whole blood (without gel separator)
- Store the clearly identified tube of whole blood at 5°C ± 3°C
- Send this tube to Biomnis at **5°C ± 3°C**

Step 2

5FUEN

Phenotyping of DPD activity using uracil and dihydrouracil levels*

- Draw 2 x 4 ml Lithium Heparin whole blood (without gel separator) and process the samples **within a strict maximum of 1 hour of drawing**:
  - Centrifuge the tubes at 2000–2200 g for 10 minutes (at 5°C ± 3°C if a temperature-controlled centrifuge is available)
  - Decant the plasma into 2 clearly identified polypropylene tubes
  - Freeze the 2 tubes of plasma immediately to < –18 °C
- Send the 2 tubes of frozen plasma to Eurofins Biomnis at < -18°C

NB : As the pre-analytical conditions are different for these two analyses, yellow **"MIXED TEMP"** labels should be attached directly to the transport bags.

** Associated tests that must be performed simultaneously.*

MIXED TEMP