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Declaration of consultation and consent

for testing of an individual's genetic characteristics

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, 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 physician

Consent for performing examinations of an individual's genetic characteristics

In accordance with 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 physician 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 protect 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:

Form RQF733
Issue Number: 2.03
Active Date: 20.03.2018

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Protocol

Evaluation of the risk of toxicity

to Fluoropyrimidines and PK Dose Adjustment of 5-fluorouracil

5-FU ODPM TOX TM — 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

Genotyping of *DPYD* gene*

- Draw 1 x 4 ml Lithium Heparin Whole Blood (without gel separator) ***(green cap)***
- 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

Phenotyping of DPD activity using uracil and dihydrouracil levels*

- Draw 2 x 4 ml Lithium Heparin Whole Blood (without gel separator) ***(green cap)*** 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
  - 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 FILE"** labels will be attached directly to the transport bags.

MIXED FILE

** Associated tests that must be performed simultaneously.*

5-FU ODPM PROTOCOL TM — PK GUIDED DOSE ADJUSTMENT OF 5-FLUOROURACIL

NB : For 46 hour infusions, please draw between the 16th and 43rd hour.

- Draw 2 x 4 ml tubes with lithium-heparin without gel separator ***(green cap)*** 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
  - 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 **< -18°C**

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