MEDICAL PRESCRIPTION FOR ISET® BLOOD CYTOPATHOLOGY

PLEASE FILL THE FORM CLEARLY IN CAPITAL LETTERS ONLY

EN20180315

PATIENT – CONTACT DETAILS

SURNAME: …….…….. MAIDEN NAME: ……..…….

NAME: ……..... …… DATE OF BIRTH: …….

SEX: ☐ F ☐ M

EMAIL ADDRESS: ……... PHONE No: ……

POSTAL ADDRESS: ……

……..

CERTIFICATION OF INFORMATION RECEIPT AND CONSENT

NATURE OF THE TEST

The ISET® Blood Cytopathology test is an innovative method that detects the non-blood cells (i.e. other than platelets, white and red blood cells) in the blood. These cells are called "Circulating Rare Cells" (CRCs) because they are very rare and not detectable by routine blood tests. These CRCs are of different types and can include cells derived from cancer. The Rarecells® Device isolates the CRCs from blood and allows their identification by cytomorphological analysis. Circulating Cancer Cells (CCCs) could be present between the CRCs. The ISET® technique allows the detection and quantification of the CCCs (Circulating Cancer Cells) in the blood. This analysis is both qualitative and quantitative.

The ISET® Blood Cytopathology analysis identifies the possible invasion of the blood by the tumor at the time of the blood draw.

INDICATIONS OF THE TEST

The ISET® Blood Cytopathology test is the most sensitive known method for the detection of CCCs. It can be offered in the following situations:

- Patients with solid cancer at diagnosis: to perform a more accurate and thorough staging of the cancer and determine the best therapeutic strategy
- Patients with solid cancer in remission: for monitoring and early detection of risks of recurrence
- Patients with solid cancer at an invasive stage: to evaluate the response of CCCs to treatment (the treatment is effective if the CCCs disappear)

The analysis is valid for any type of solid cancer (any type of cancer except leukemia and lymphomas). This test is not a medical diagnosis.

RECOMMENDATIONS AND RISKS

The ISET® Blood Cytopathology test is based on a blood draw. **For patients with cancer diagnosis already established, blood collection for the ISET® Blood Cytopathology test must not be made soon after an invasive procedure (biopsy, surgery, functional tests). Waiting a minimum of four weeks is necessary in order to identify the spontaneous circulation of CCC in the blood (tumour invasion).** The only risks of the ISET® Blood Cytopathology test are the possible complications associated to a blood draw (hematoma at the puncture site, temporary faintness ...).

LIMITATIONS OF THE TEST AND INFORMATION IF THE TEST IS PERFORMED ON PATIENTS WITHOUT DIAGNOSED CANCER*

For patients without a diagnosed cancer, the ISET® Blood Cytopathology test could be performed only with a "Medical Prescription for ISET® Blood Cytopathology" duly filled in by a physician and the patient. . It is however necessary to remind patients that only 1 scientific study concerning this application has been published*. In case of positive results, the test does not indicate the organ of origin of the CCCs and it cannot foretell the time lapse before identification of the tumor by imaging is possible. The positive result of the test carried out in the absence of a diagnosed cancer indicates the need for monitoring of the subject with the usual methods to be evaluated by your physician (imaging, blood tests, endoscopy... etc.).

*The use of the ISET® Blood Cytopathology test for health monitoring and early detection of invasive cancer refers to the publication "Ilie M et Al, 2014**, a 6-year monocentric study. Other similar clinical research studies are ongoing, including multicenter validation studies. At this time, their result is yet unknown.

**Ilie M et al: 'Sentinel'' Circulating Tumor Cells Allow Early Diagnosis of Lung Cancer in Patients with Chronic Obstructive Pulmonary Disease, PlosOne 2014.

RESULTS

The usual period to obtain the results is 15 working days (3 weeks) after the filter ISET® reaches the Cytopathology Centre. In exceptional cases the period may be 20 working days. The sensitivity of CCCs isolation by the ISET® technology is one CCC in 10ml of blood. The specificity is determined by a microscopic examination performed by

experienced cytopathologists. The ISET® technology has been validated by more than 50 high-level scientific publications (see www.rarecells.com and www.isetbyrarecells.com) involving more than 2000 patients. If blood draw recommendations have been followed, a positive result (presence and number of CCCs) indicates the tumour invasion of the blood compartment.
A negative result means that the patient's blood does not contain CCCs at the time of the test. In the rare case of difficulties of implementation and / or interpretation of the test, a new analysis will be performed at no charge.

PATIENT INFORMED CONSENT: ISET® BLOOD CYTOPATHOLOGY

I, the undersigned M, Mrs., Ms., (name, surname, maiden name):
……-

- Certify having received on this day accurate, clear and appropriate information (see text above) which includes: the characteristics of the ISET® Blood Cytopathology; its indications, recommendations, limitations and risks; modalities for payment and the delivery of results.

- Freely request to perform the analysis ISET® Blood Cytopathology for the detection of Circulating Rare Cells (CRCs)

☐ **I agree to donate** anonymously my clinical data and results of my medical biology and anatomopathology examinations collected at the time of blood draw for the ISET® Blood Cytopathology by the medical examination laboratory, in charge of these examinations and responsible of data treatment, to any organization and biomedical team, public or private, for the purpose of medical research, investigations, medical statistics, and diagnostic and therapeutic evaluation to help the research against cancer. I will also receive at the time of the blood draw for the ISET® Blood Cytopathology by the laboratory in charge of data treatment, a complementary information note concerning my rights about my personal data treatment.

☐ **I refuse to donate** my clinical data and the results of my medical biology and anatomopathology examinations to help the research against cancer.

The undersigned doctor keeps a copy of this document and gives me the original to be handed over to the laboratory performing the blood draw.

PHYSICIAN'S INFORMATION CERTIFICATION:

I, the undersigned Doctor.....
Certify having received for consultation the aforementioned patient on this day and have explained to him/her precisely the purpose, modalities and limitations of the ISET® Blood Cytopathology test and ask the laboratory to perform, for the above mentioned patient, an ISET® Blood Cytopathology analysis.

PATIENT:	**PHYSICIAN:**
Date and signature:	Surname, Name: Email: Phone: Date: Stamp and Signature:
MEDICAL EXAMINATION LABORATORY	
Date of blood draw:	Laboratory stamp:

Note: ISET® is a registered trademark which guarantees the excellence of each step for the realization of the ISET® Blood Cytopathology test.

Note: The requested medical information (see here-after) are essential to the cytopathologist. For example, some treatments may damage the cells in the blood, moreover some cancers are characterized by more or less atypical tumor cells. You are kindly asked to supply as much information as possible on the following forms.

RELEVANT MEDICAL INFORMATION FOR THE ISET® BLOOD CYTOPATHOLOGY ANALYSIS

PLEASE, FILL THE FORM IN CLEARLY AND IN CAPITAL LETTERS ONLY

Have you ever had been diagnosed with cancer ? Yes ❑ No ❑

If you answered YES, please fill in carefully sections A and B (by your physician and/or yourself)

If you answered NO, please fill in section B only (by your physician and/or yourself)

SECTION A - Cancer Diagnosis	
Information about your cancer	**Cancer Staging at diagnosis**
Type of cancer (organ): _____ _____ Date of diagnosis: _____ Histological Type: _____ _____ TNM Classification: _____ Grade : _____	Size of the tumor: _____ Lymph nodes involved: Yes □ No □ If Yes, how many and localization: _____ _____ Presence of metastases: Yes □ No □ If Yes, how many and localization: _____ _____
Therapies Administered	**Date et type of last treatment(s)**
□ Preoperative Chemotherapy: _____ _____ □ Surgery: ○ N° of surgical interventions: _____ _____ ○ Dates and anatomical districts: _____ _____ □ Preoperative Cancer Staging: Lymph nodes involved: Yes □ No □ If Yes, how many and localization: _____ _____ Presence of metastases: Yes □ No □ If Yes, how many and localization: _____ _____ □ Postoperative Chemotherapy and/or hormonotherapy (Type and dates): _____ _____ _____ _____ □ Radiotherapy (Date and localization): _____ _____	Surgery (dates): _____ _____ Radiotherapy (dates): _____ _____ _____ Chemotherapy (dates): _____ _____ _____ _____ Hormonotherapy (dates): _____ _____

SECTION B – Information about your previous cancer family history and your life habits

Have you ever had a family member diagnosed with cancer ? Yes ❑ No ❑

- Degree of relationship: _____
- Type of cancer: _____
- Age at diagnosis: _____

- Degree of relationship: _____
- Type of cancer: _____
- Age at diagnosis: _____

- Degree of relationship: _____
- Type of cancer: _____
- Age at diagnosis: _____

Life Habits

☐ Alcohol – Wine – n° of glasses: _____

- Daily: _____
- Weekly: _____
- N° of years: _____

☐ Alcohol – Spirits – Type: _____

- N° of glasses: _____

- Daily: _____
- Weekly: _____
- N° of years: _____

☐ Tobacco

- Type (cigarettes, cigars, other): _____
- How many per day: _____
- N° of years: _____

☐ Sport Activities (please, specify):

_____

_____

☐ Ongoing and past treatments (ex. hormones):

_____

_____

☐ Ongoing treatments:

_____

_____

Inflammatory / Autoimmune Pathologies

☐ Bronchitis:

_____

☐ Intestinal:

_____

☐ Hepatitis:

_____

☐ Coagulation Pathologies:

_____

☐ Contact with toxic substances: professional or occasional exposure (i.e. painters, gas station attendants, workers exposed to pesticides, etc…):_____

_____

_____

_____

☐ Autoimmune Pathologies:

_____

_____

☐ Others : _____