

## 1. Scope and Application

These guidelines provide information for the correct completion of the Oncology Request Form. This form is used by the pathologist requesting tests to be performed on diagnostic samples (paraffin blocks or slides and plasma samples) at CellCarta.

## 2. Abbreviations and definitions

- BSM — Biosample Management
- CSA — Clinical Study Associates
- FFPE — Formalin-Fixed Paraffin Embedded
- FISH — Fluorescence in situ Hybridization
- HER2 — Human Epidermal Growth Factor Receptor 2
- RIZIV — Rijksinstituut voor ziekte- en invaliditeitsverzekering
- REQUESTOR — The requesting pathologist

## 3. Responsibilities

It is the duty of the requesting pathologist to complete and sign the Oncology Request Form. A poor standard of completion of the form may represent a threat to the patient's treatment and health.

The CellCarta BSM and CSA teams are responsible for reviewing whether or not the Oncology Request Form has been completed correctly. If data are lacking or whenever uncertainty exists on the identification of a sample, the BSM and CSA teams have the responsibility to contact the responsible CellCarta project manager who will subsequently contact the requesting pathologist (or pathology lab). The requested analyses will not be performed until all required information has been obtained. The CellCarta BSM and CSA teams are responsible for correct entry of all data into the database.

### 4.1. Procedure: Minimum criteria

The minimum criteria for completion of the Oncology Request Form are:

- Patient Family Name
- Patient First Name
- Patient Date of Birth
- Patient National Registry ID
- Requestor Family Name
- Requestor First Name
- Requestor Identification number (RIZIV Number)
- Requestor Address
- Date of Request
- Requestor Signature
- Local Sample Number
- Local Block Number
- Paraffin Block/Sections or plasma
- Fixative used
- Fixation time (when FISH testing is requested)
- Date of tissue collection
- Tests Requested

On the sample block and/or slides, at least one identifier (e.g. local block number) must be present matching the identifier(s) on the accompanying Oncology Request Form.

### 4.2. Completion of the Oncology Request Form

The Oncology Request Form must be completed using black or blue-black ink. A separate form must be used for each patient.

#### **4.2.1. Patient Details - MANDATORY**

If possible, the use of National Health Service patient labels is preferred. If not available, the following data must be provided: patient family name, patient first name and date of birth.

#### **4.2.2. Applicant Details - MANDATORY**

Family name, first name, identification number (RIZIV number) and address of the requestor must be provided. Alternatively, an identification stamp of the requestor can be used if the entry is signed to authenticate it. The contact coordinates (including e-mail address) of each requestor will allow for correct reporting through the CellCartaCustomer Portal. The requestor must date and sign the completed Oncology Request Form.

#### **4.2.3. Tissue and Processing Information - MANDATORY**

The local sample number is the block identifier assigned by the local pathology laboratory. The local block number is the subsample number (e.g. 1 to 20) assigned to the specific tissue subsample from that patient. The local sample number is identical for the different samples procured from a single patient at a certain point in time. These identifiers are essential to link the tissue sample to the patient identifiers.

In addition, the sample type, being paraffin block(s)/section(s) or plasma and the number of blocks, slides and/or plasma samples should be indicated to enable the CellCartaemployees to check whether the shipment arrived in its entirety.

Information on fixation is mandatory and gives important information allowing for correct interpretation of test results: fixatives other than formalin (buffered neutral), such as those containing picric acid, may damage nucleic acids and may therefore cause invalid test results. Not only the type of fixation but also fixation time may influence test results. Ideally, FFPE samples should be fixed between 6 and 48 hours in neutral buffered formalin. It is important to inform CellCartaabout over-fixed samples (e.g. weekend samples), because for some tests the slide pre-treatments are adapted accordingly.

Also information on date of tissue collection is mandatory and needs to be provided on the Oncology Request Form.

#### **4.2.4. Tests Required - MANDATORY**

The requested tests should be ticked off. Whenever HER2 FISH analysis is requested, the result of the HER2 IHC test should be ticked off and sites are requested to add the HER2 IHC stained slide.

**Updated on 11 June 2019**