for inter-laboratory tests for predicting the survival and treatment response of patients with cancer.

In one aspect, there is provided a method for assessment of a number or density of immune cells in tumoral tissues comprising the steps consisting in: a. providing one or more immunostained slices of tissue section obtained by an automated slide-staining system by using antibodies binding specifically to antigens (markers) expressed by immune cells; b. proceeding to digitalisation of the slides of step a. by high resolution scan capture, whereby a high definition (4.6 µm/pixel or better) digital picture of the slide to be analysed is obtained; c. detecting the slice of tissue section on the digital picture; d. analyzing the slice of tissue section for defining (i) a tumour (CT) and (ii) an invasive margin of the tumour (IM); e. providing a size reference grid with uniformly distributed units having a same surface, said grid being adapted to the size of the tumour to be analysed; e1. checking the quality of immunostaining; f. detecting and quantifying stained cells of each unit whereby the number or the density of immune cells stained of each unit is assessed.

The new method has particularly fewer problems with repeatability and reproducibility when compared to the method of EP-A-EP1943520 and WO2007045996

DESCRIPTION OF THE PREFERRED EMBODIMENTS

A subject of the present application is therefore a method for assessment of a number or density of immune cells in tumoral tissues comprising the steps consisting in:

a. providing one or more immunostained slices of tissue section obtained by an automated slide-staining system by using antibodies binding specifically to antigens expressed by immune cells.

b. proceeding to digitalisation of the slides of step a. by high resolution scan capture, whereby a high definition (4.6 µm/pixel or better) digital picture of the slide to be analysed is obtained,

c. detecting the slice of tissue section on the digital picture

d. analyzing the slice of tissue section for defining (i) the tumour (CT) and (ii) the invasive margin of the tumour (IM),

e. providing a size reference grid with uniformly distributed units having a same surface, said grid being adapted to the size of the tumour to be analyzed,

f. detecting and quantifying stained cells of each unit whereby the number or the density of immune cells stained of each unit is assessed.

Typically, the antibodies are specific for a protein expressed by an immune cell and more particularly are specific for an immune cell surface marker. For example, the antibodies may be specific for a marker as described in WO2007045996, immune cells considered may be B cells and preferably T cells. For example, the T cells of the invention are T cells of sub groups CD3+ cells (T cells), CD8+ cells or GZMB+ cells (cytotoxic T cells), CD4+ cells (T helper cells), CD45RO+ cells (memory T cells). In a particular embodiment, the antibodies are specific for CD3, CD4, CD8, CD20, CD45RO, and GZMB markers.