

# MAMMATYPER®

## The solution for your breast cancer diagnostics

### Background & Introduction

The 12<sup>th</sup> and 13<sup>th</sup> St Gallen International Breast Cancer Conference Expert Panel, which recommends breast cancer diagnosis and treatment guidelines for Europe, recommended in 2011 and 2013, respectively, that all breast cancer be routinely subtyped using a combination of four genetic markers estrogen receptor (ER), progesterone receptor (PR), human epidermal growth factor receptor 2 (HER2) and the marker of proliferation Ki-67.

It is generally established, that the stratification of breast cancer into *Luminal A-like*, *Luminal B-like (HER2 negative)*, *Luminal B-like (HER2 positive)*, *HER2 positive (non-luminal)* and *Triple negative (ductal)* breast cancer tumor subtypes is mandatory to provide the best treatment decisions. Therefore, precise sub-classification of breast cancer is an essential part of successful cancer treatment.

The current routine method for classifying breast cancer is immunohistochemistry (IHC), a long established test procedure, which is semi-quantitative in nature and has shown variable test results for each of the four genetic markers\*. Mainly for the cell proliferation marker Ki-67, IHC-based test systems have been shown to be limited in precision and reproducibility resulting in inaccurate determination of breast cancer subtypes (*Journal of the National Cancer Institute 2013; 1897-1906; Polley et al.*).

MammaTyper® overcomes these major disadvantages by measuring the mRNA expression of the aforementioned well-known tumor markers using the quantitative RT-qPCR technology.

#### MammaTyper® kit:

- Allows a **precise, reproducible** and **quantitative** measurement of the breast cancer markers **ESR1, PGR, ERBB2** and **MKI67** by determining the **mRNA expression level from FFPE tissue**
- Provides **reliable classification** into **Luminal A-like, Luminal B-like (HER2 negative), Luminal B-like (HER2 positive), HER2 positive (non-luminal) and Triple negative (ductal)** breast cancer subtypes
- Provides **information on patients' prognosis**
- Has the potential to **predict chemotherapy benefit**
- Can be **performed** in **any pathology laboratory** with **same day results**

\*(*The Oncologist* 2008; 13:1134–1136; Allred *et al.*): The consequences of this variability were starkly shown in 2007 in a study undertaken in Canada. The Canadian study demonstrated that of 2000 breast cancer patients originally classified as estrogen negative using IHC, 40% were subsequently found to be estrogen positive. Further, meta-analysis conducted by the American Society of Clinical Oncology (ASCO) has shown that up to 20% of IHC breast cancer testing is inaccurate for each of the major sub-typing tests performed.

## Why MammaTyper®?

MammaTyper® kit is a molecular *in vitro* diagnostic test based on RT-qPCR technology that allows a quantitative detection of the mRNA expression levels of the four well established biomarkers of breast cancer tumors recommended by the St Gallen Expert Committee (*Annals of Oncology 2011; 22: 1736-1747; Goldhirsch et al.; Annals of Oncology 2013; 10: 1093; Goldhirsch et al.*). The test is applicable for all female patients with newly diagnosed invasive breast cancer. The application of MammaTyper® has the potential to significantly improve the standard treatment of breast cancer patients.

ERBB2	ESR1	PGR	MKI67	St. Gallen 2013 Surrogates
pos	pos	pos	pos	Luminal B-like (HER2 positive)
pos	pos	pos	neg	Luminal B-like (HER2 positive)
pos	pos	neg	pos	Luminal B-like (HER2 positive)
pos	pos	neg	neg	Luminal B-like (HER2 positive)
pos	neg	pos	pos	not defined acc. to St. Gallen class. 2013*
pos	neg	pos	neg	not defined acc. to St. Gallen class. 2013*
pos	neg	neg	pos	HER2 positive (non-luminal)
pos	neg	neg	neg	HER2 positive (non-luminal)
neg	pos	pos	pos	Luminal B-like (HER2 negative)
neg	pos	pos	neg	Luminal A-like
neg	pos	neg	pos	Luminal B-like (HER2 negative)
neg	pos	neg	neg	Luminal B-like (HER2 negative)
neg	neg	pos	pos	not defined acc. to St. Gallen class. 2013*
neg	neg	pos	neg	not defined acc. to St. Gallen class. 2013*
neg	neg	neg	pos	Triple negative (ductal)
neg	neg	neg	neg	Triple negative (ductal)

Tab. 1: Subtype definition according to 13<sup>th</sup> St Gallen guidelines (Goldhirsch et al. 2013)

\*The US SEER breast cancer surveillance program found 2.4% of all BC patients in the ER-/PR+ subclass (Ries LAG, Young JL, Keel GE, Eisner MP, Lin YD, Horner M-J). SEER Survival Monograph: Cancer Survival Among Adults: U.S. SEER Program, 1988-2001, Patient and Tumor Characteristics. National Cancer Institute, SEER Program, NIH Pub. No. 07-6215, Bethesda, MD, 2007; Table 13.10)

MammaTyper® provides an objective and reliable classification of breast cancer tissue into Luminal A-like, Luminal B-like (HER2 negative), Luminal B-like (HER2 positive), HER2 positive (non-luminal) and Triple negative (ductal) tumor subtypes. Furthermore, the test provides prognostic information regarding a patient's risk for distant metastases and her overall survival. Additionally the test has the potential to provide predictive information on chemotherapy benefit.

**MammaTyper® is now available as CE/IVD marked kit in Europe and certain other countries.**

For further information please contact our customer service.

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