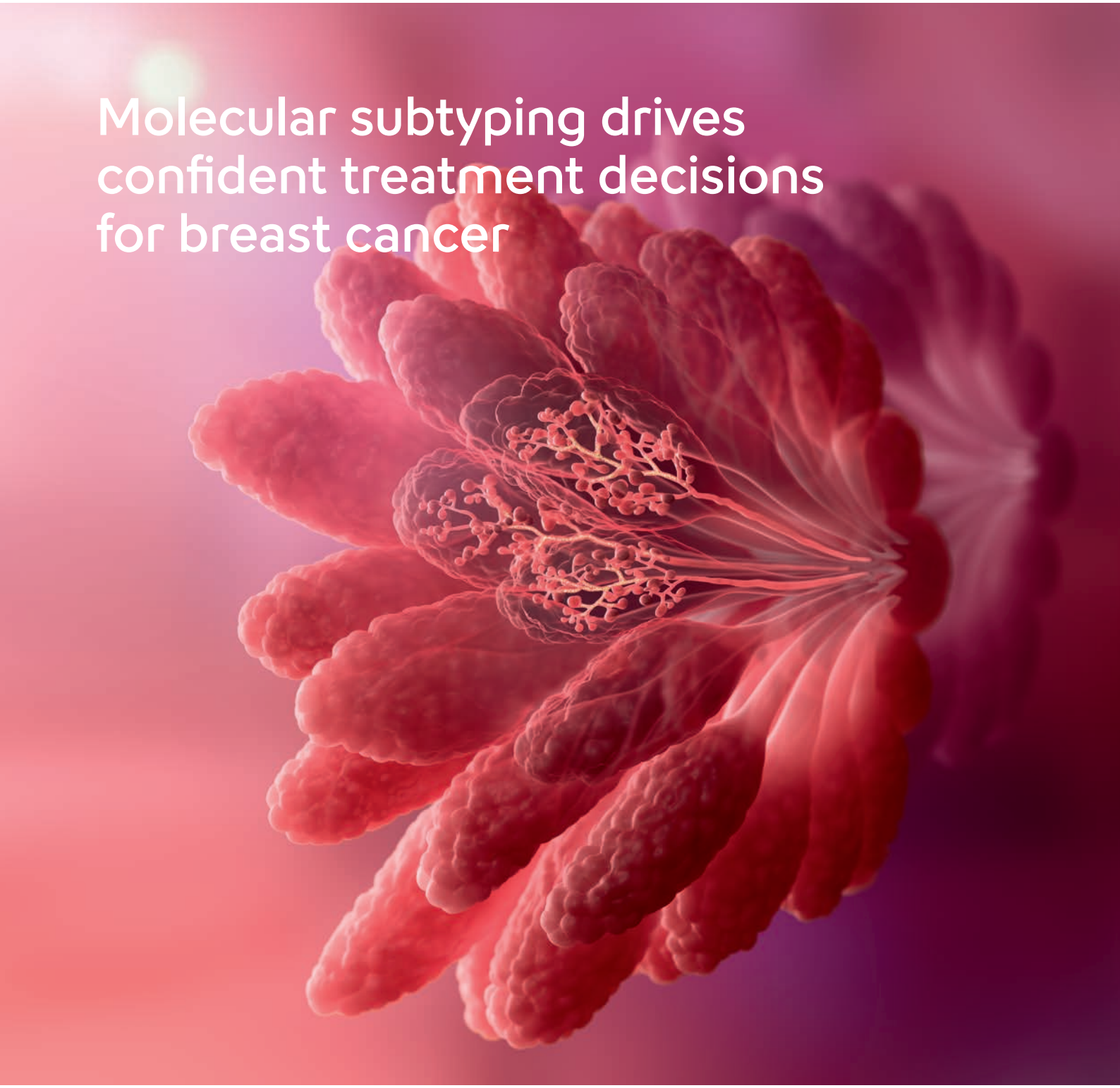
sysmex | Together for a better healthcare journey

MammaTyper®

Molecular subtyping drives confident treatment decisions for breast cancer



Molecular subtyping is essential for subsequent treatment decisions in breast cancer

All invasive breast cancer tumours are tested for the molecular subtype, which is essential for deciding the subsequent treatment of the patient and gives an indication of the prognosis. With more treatment options becoming available, increasingly accurate molecular subtyping is required. Current methods lack standardisation, reproducibility and quantification.

MammaTyper® precisely quantifies expression of HER2, ER, PR and Ki-67 mRNA

MammaTyper® is a molecular diagnostic test for quantitative determination of the four key biomarkers used in the subtyping of breast cancer. Human epidermal growth factor receptor 2 (HER2), estrogen receptor (ER), progesterone receptor (PR) and the marker of proliferation Ki-67 are key biomarkers in the evaluation of breast cancer tumours. The combination of biomarker results allows the assessment of the different St. Gallen breast cancer subtypes which are key parameters for treatment decisions.

Definition of breast cancer surrogate subtypes the St. Gallen classification [1].

Breast cancer subtypes	ER	PR	HER2	Ki-67
Luminal A-like	Pos	Pos	Neg	Neg
Luminal B-like (HER2-negative)	Pos	Pos/Neg*	Neg	Pos/Neg*
Luminal B-like (HER2-positive)	Pos	Pos/Neg	Pos	Pos/Neg
HER2-positive (non-luminal)	Neg	Neg	Pos	Pos/Neg
Triple-negative (ductal)	Neg	Neg	Neg	Pos/Neg

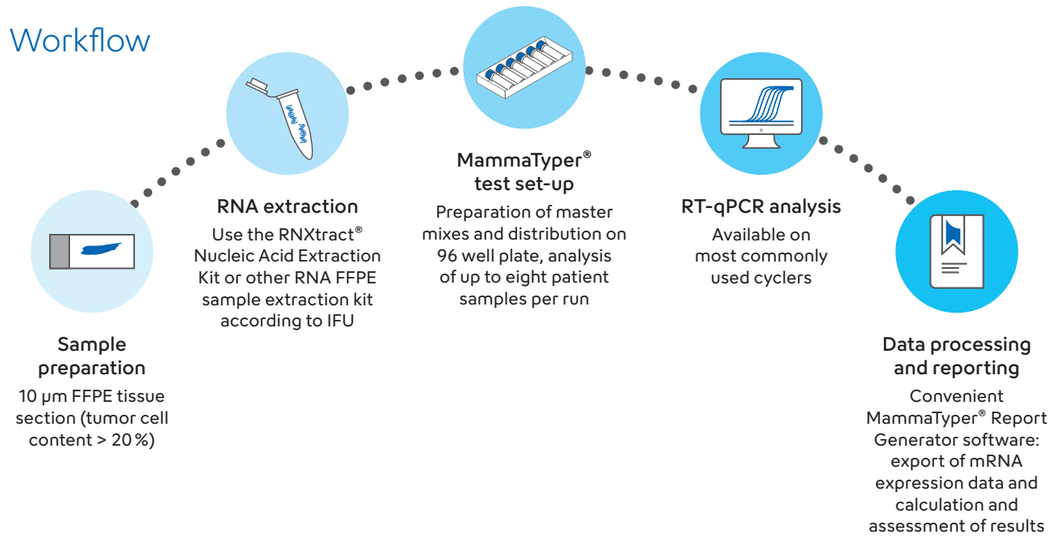
* With the exception of the combination PR pos and Ki-67 neg = Luminal A-like

[1] Harbeck N et al. (2013): Breast Care; 8 (2), 102–9.

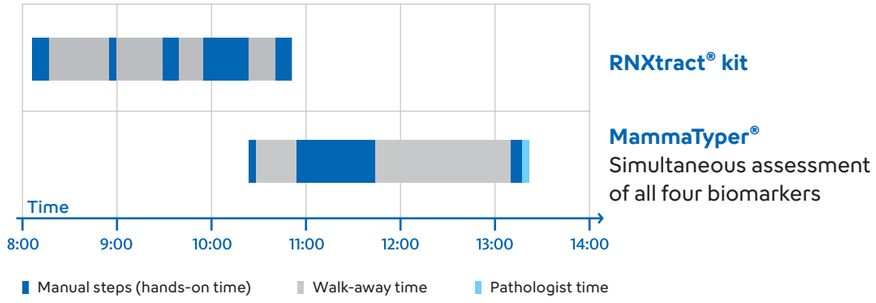
MammaTyper® key facts

- ✔ CE-marked IVD RT-qPCR assay for most commonly available thermocyclers
- ✔ Quantitative, reproducible and observer-independent testing
- ✔ Results within the same day because of the fast turnaround time
- ✔ Precise determination of HER2, ER, PR and Ki-67 in one assay
- ✔ Standardised and fast molecular subtyping, enabling confident treatment decisions

Workflow



Start to finish: 5 – 6 hours

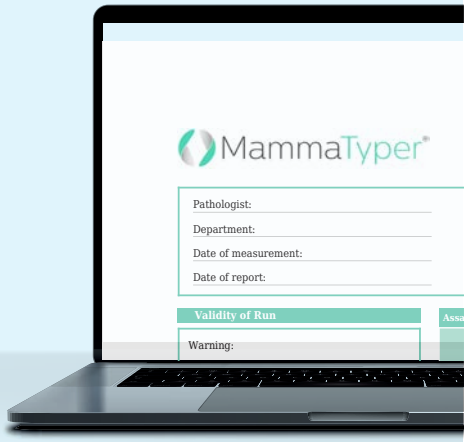


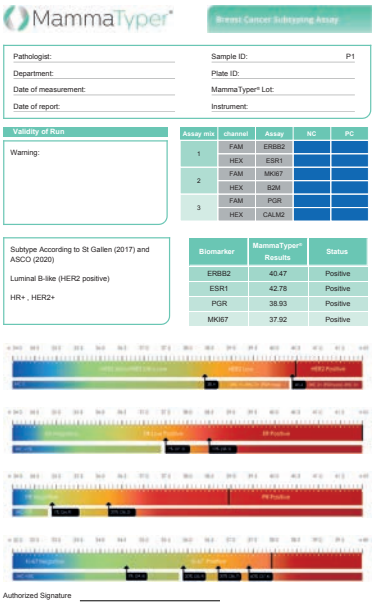
RNXtract® kit key facts

- ✔ Complementary CE-marked IVD product to the MammaTyper® kit
- ✔ Faster procedure eliminates the need for a column system in nucleic acid purification by utilising magnetic beads
- ✔ Environmentally friendly and safer for users as it does not utilise a deparaffinisation reagent and reduces plastic material waste

MammaTyper® report example

RT-qPCR results are plotted against defined IHC correlating cut offs.





MammaTyper® specifications

Product	MammaTyper® IVD test kit (10 reactions)
Sample type	10 µm FFPE tissue section (tumour cell content > 20 %)
Sample capacity	up to 8 patient samples per kit
QC function	2 external controls (positive + negative)
Compatible platforms	most common thermocyclers

Discover more on our website www.sysmex-europe.com/MammaTyper

RNXtract® specifications

Product	RNXtract® Nucleic Acid Extraction Kit
Sample type	10 uM FFPE tissue section (tumor cell content > 20 %)
Sample capacity	48 extractions

Discover more on our website www.sysmex-europe.com/RNXtract

Distributor EMEA: Sysmex Europe SE · www.sysmex-europe.com
Manufacturer: Cerca Biotech GmbH · www.cercabiotech.com
This product may not be available for sale in all countries. Please contact your Sysmex representative for availability.
You will find your local Sysmex representative's address under www.sysmex-europe.com/contacts

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