
## Innovation for your breast cancer diagnostics

- Reliable
- Precise
- Reproducible

- Molecular *in vitro* diagnostic test for the breast cancer biomarkers *ERBB2*, *ESR1*, *PGR* and *MKI67*
- Quantitative determinations of mRNA expression of each marker via RT-qPCR
- Precise molecular subtyping of tumor tissue acc. to St Gallen Guidelines
- From biopsy FFPE sample to result in 1 day
- Applicable in any molecular pathology

## Reliable and accurate subtyping with MammaTyper®

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|---|---|
| High performing | › Precise determination of mRNA expression of the four essential breast cancer biomarkers *ERBB2* (HER2), *ESR1* (ER), *PGR* (PR) and *MKI67* (marker of proliferation Ki-67).<br>› Accurate molecular subtyping 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)* tumors (according to St Gallen classification 2013). |
| Innovative | › RT-qPCR technologies open up new dimensions in breast cancer diagnostics. It has a series of widely acknowledged methodologial advantages and it is quantitative by nature with a wide dynamic range. |
| Validated | › More than 800 analyzed patient samples in retrospective clinical performance evaluation studies.[1,2] |
| Objective | › Reliable quantitative values per marker. Each marker is classified as positive or negative according to validated cut-off values. |
| Optimized | › Minimized intra-/inter-laboratory variations and highly reproducible results.[3]<br>› Easy to handle and same day results. |
| Prognostic | › Extended information for patient's risk of developing distant metastases and overall survival based on precise subtyping.[1] |
| Predictive | › Information for treatment selection based on accurate subtyping and benefit of (neo) adjuvant chemotherapy and endocrine therapy.[1,2] |

1) Wirtz et al.,"*Biological subtyping of early breast cancer: A study comparing RT-qPCR with immunohistochemistry*", Breast Cancer Res. Treat. (2016): DOI 10.1007/s10549-016-3835-7
2) Sinn et al.,"*Comparative analysis of quantitative IHC with automated scoring versus reverse transcription quantitative real-time PCR on FFPE tissue samples for the assessment of ER, PR and Ki-67 labeling index and the prediction of pathological complete response in breast cancer.* ", submitted.
3) Laible et al.,"*Technical validation of an RT-qPCR in vitro diagnostic test system for the determination of breast cancer molecular subtypes by quantification of ERBB2, ESR1, PGR and MKI67 mRNA levels from formalin-fixed paraffin-embedded breast tumor specimens.* ", submitted.

# MAMMATYPER®

# AT A GLANCE:

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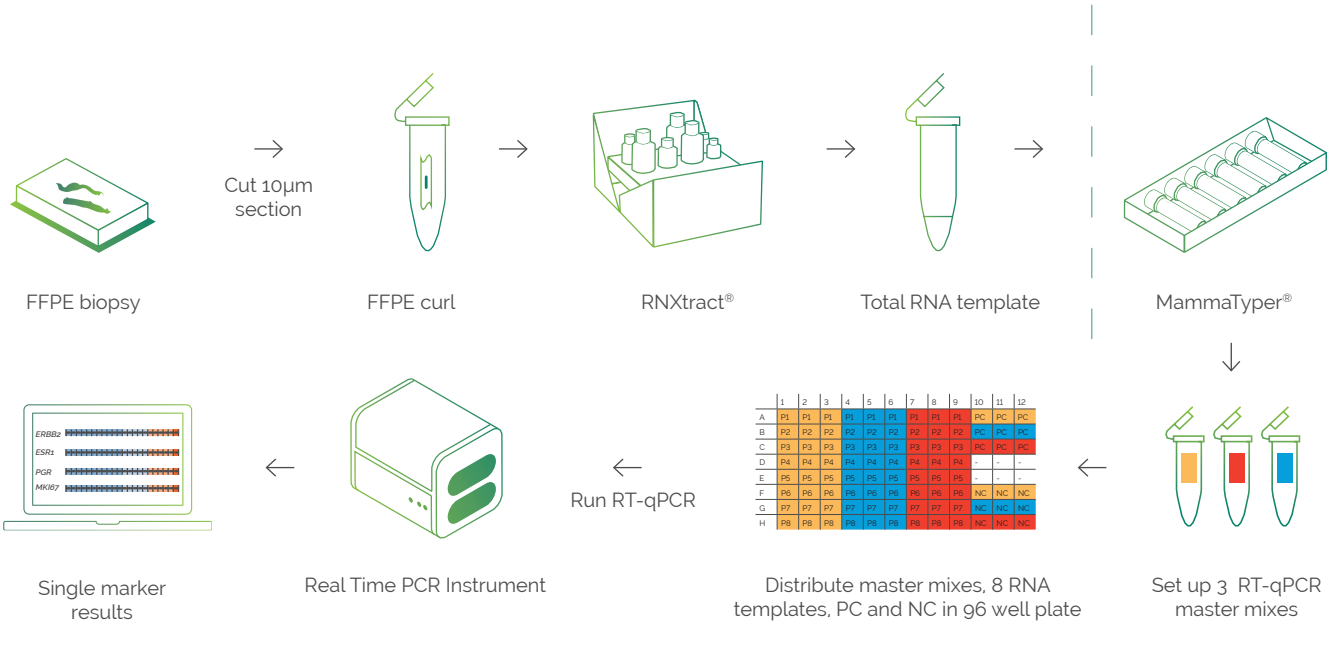
|---|---|
| Technology | RT-qPCR |
| Size | 10 determinations (max. 8 patient samples) |
| Sample material | Total RNA of FFPE tumor samples with at least 20% tumor content |
| Processing | Manual |
| Time per run | 150 min |
| Primary results | Quantitative single marker results (40-ΔΔCq) |
| Secondary results | Dichotomized single marker results, St Gallen Subtype , prognostic and predictive information |
| Validated instruments | LightCycler® 480 II, Versant® kPCR Cycler, ABI 7500 Fast and cobas z 480 Analyzer |

## MammaTyper® Workflow

**Step1:** RNXtract® sample preparation

**Step2:** MammaTyper® test preparation and execution




**For further information please contact us!**



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