MammaPrint® + BluePrint® Clinical Utility Immunohistochemistry with Ki67 versus gene expression profiling

MAMMAPRINT+BLUEPRINT
Illuminating Tumor Biology

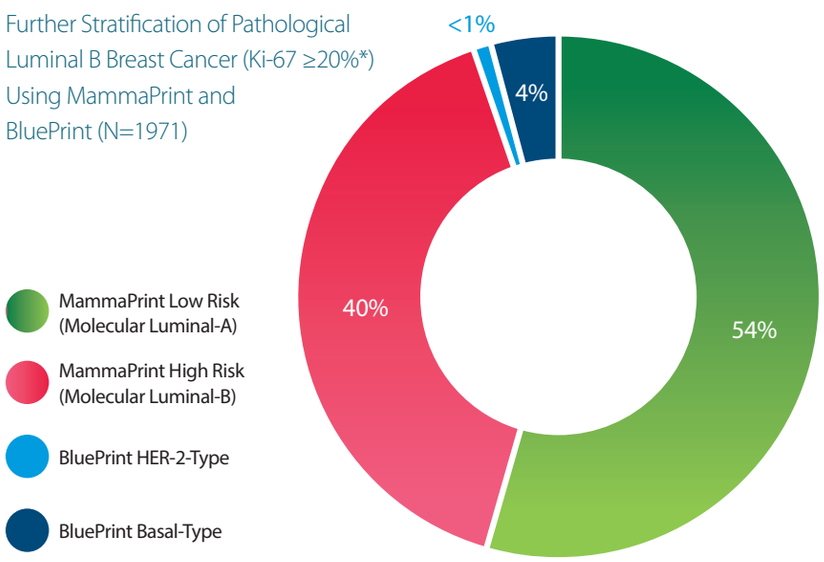
"MammaPrint and BluePrint can help to identify a larger group of patients with low risk of recurrence with similar DMFS compared with the more contemporarily used classification methodology including high-quality assessed Ki67."[1]

Further classification of St. Gallen pathological subtypes with Ki67 based on molecular (MammaPrint and BluePrint) subtyping in MINDACT

Over half (54%) of patients with pathological Luminal B breast cancer (**Ki-67 ≥20%***) were reclassified as molecular Luminal A by MammaPrint Low Risk — offering a more precise stratification without compromising patient outcomes.

*Pathological Luminal B: ER-positive AND [PgR low(<20%) AND/OR Ki67 high (≥20%)]

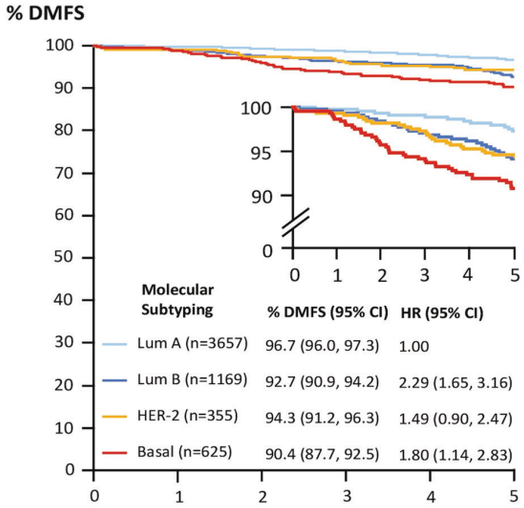
Further Stratification of Pathological Luminal B Breast Cancer (Ki-67 ≥20%*) Using MammaPrint and BluePrint (N=1971)



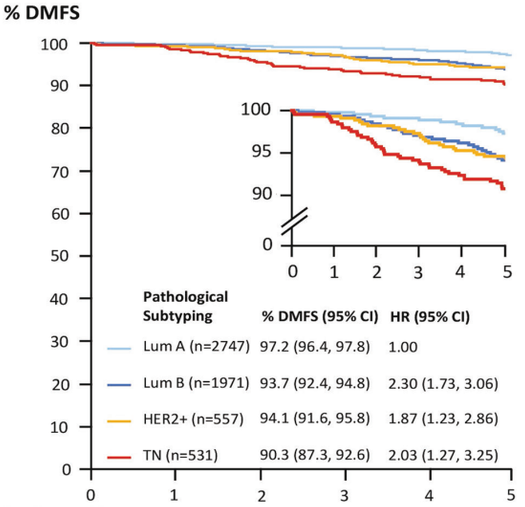
MammaPrint® + BluePrint®
63% of patients is molecular Luminal-A
5-year DMFS: 96.7%

Immunohistochemistry with Ki67
47% of patients is pathological Luminal-A
5-year DMFS: 97.2%

a



b



Moderate reproducibility of Ki67 Due to Laboratory Variability

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Ki67 Reproducibility Study Main Findings by International Ki67 in Breast Cancer Working Group

In a study[2] with 8 leading laboratories across Europe and North America, inter-laboratory reproducibility was only moderate:

- Central staining ICC† = 0,71
- Local staining ICC† = 0,59

† ICC has a range of 0 to 1, with 1 denoting highest agreement, and scores ≥0.9 are necessary for good reproducibility

Variations were caused by differences in tumor region selection, counting methods and subjective assessment

High Accuracy of MammaPrint

Independent inter-laboratory studies conducted in CLIA-certified laboratories in the Netherlands and the US:

Accuracy of classification as high/low risk: **97.3%**

Repeatability of measurements: **97.8%**

Reproducibility measured on 300 control samples: **99%**

These results confirm that MammaPrint has robust analytical validity, with high accuracy, repeatability and reproducibility in different laboratories[3,4]

AGENDIA® MAMMAPRINT

Learn the likelihood of a patient's breast cancer recurring.

70-gene assay

AGENDIA® BLUEPRINT

Determine the underlying genomics driving the growth of a tumor.

80-gene assay

ICC = intraclass correlation coefficient (ICC) was used as a summary measure of reproducibility. The ICC has a range of 0 to 1, with 1 denoting highest agreement.

1 Viale, et al. BCRT 2017
2 Polley, et al. JNCI 2013
3 Sapino et al. J Mol Diagnostics 2014; 16: 190-197
4 Beumer et al. Breast Cancer Res Treat 2016

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