

Dramatically Faster Breast Cancer Recurrence Risk Profiling



About Digistain

Traditional methods of identifying biomarkers to predict breast cancer recurrence are **slow and expensive**.

Digistain has developed an MHRA-cleared technology that transforms the identification and analysis of established biomarkers from a long expensive process to a **rapid affordable solution** to identify the risk of breast cancer recurrence within the next 10 years.

How It Works

Digistain is pioneering the growing use of spectrometry in cancer diagnostics. This biopsy imaging approach enables us to:

- ✔ Measure chemical concentrations associated with tumour malignancy
- ✔ Precisely determine the characteristics of cancer cells
- ✔ Quantify validated pathology markers correlated to tumour proliferation

Our technology captures a unique spectral signature from each biopsy and performs analysis on **over 10,000 data points** per biopsy. Using this data, Digistain's proprietary artificial intelligence identifies risk profiling patterns and computes an accurate risk score – the Digistain Prognostic Score. The score provides clinicians with a single-digit number predicting the proliferation risk of sample cancer cells to guide diagnosis and adjuvant (post-surgery) chemotherapy decision-making.



Clinical Evidence

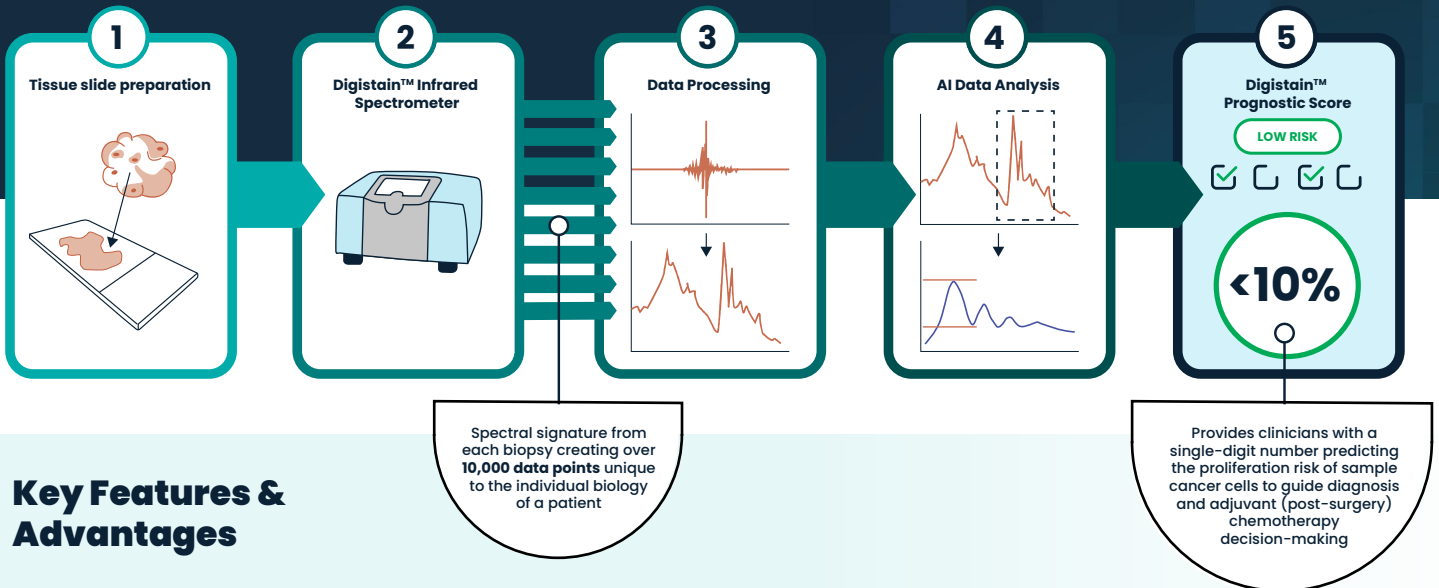
Digistain has been designed with input from over 1500 oncologists and successfully **tried by over 1200 patients** in prominent cancer centres.

A [clinical validation study](#) has demonstrated Digistain can identify cancer recurrence risk with equivalent reliability and accuracy to gold standard NICE-approved traditional tumour profiling tests in disease-free survival and overall survival prediction, with numerically equivalent sensitivity specificity and reproducibility.

Digistain cuts down wait times for results massively when compared to our current provider who is sending samples to the US for analysis. The turnaround time with Digistain is much quicker, it is more accurate and cheaper. The backlogs caused by the pandemic and industrial actions mean that fast-paced technology like this can really be the difference between life and death. "I have worked for the National Health Service for 25 years and it is innovation like this that will open up a new digital pathway and frontier for the NHS – and help future-proof it. It can only be a matter of time before Digistain is adopted across the whole of the NHS.

Sharaz Khan, NHS Head of Pathology at the Northampton General Hospital

The Process in 5 steps



Key Features & Advantages

✔ Proven

Demonstrated predictive power equivalence to best in class NICE approved tumour profiling tests.

✔ Fast

Results are quickly returned to the healthcare provider within 72 hours, thereby cutting decision times from months and weeks to hours.

✔ Accessible

Low-cost process and fast turnaround enables more patients to access the best care.

✔ Clear

Provides an easy-to-read pathology report with a clear low or high-risk score on the likelihood of breast cancer recurrence in the next 10 years.

✔ Precise

Delivers prognostic accuracy by measuring protein biomarkers, therefore, avoiding the tissue processing variability and reproducibility issues associated with traditional wet-chemistry genomic tests.

✔ Applicable

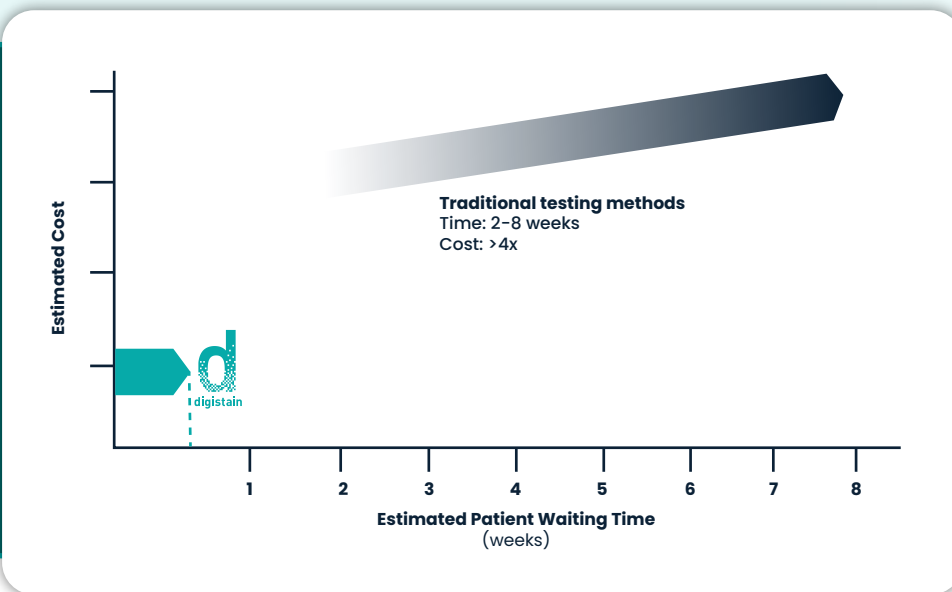
Has broad ethnic applicability and is suitable for people all around the world.

✔ Compatible

Works with current hospital diagnostic workflows, supported by robust quality management systems, and applied to already available tumour samples prepared using standard processing methods.

✔ Environmental

Avoids the high carbon footprint associated with genomic tests that require large volumes of chemical reagents and are typically only processed in the US so creating further environmental impact as samples are shipped by air.



Who is it for?

Digistain allows for borderline low risk and medium risk patients to benefit from a breast cancer recurrence risk test. It is suitable for women diagnosed with invasive breast cancer who are at Stage 1 or 2, HER2 Negative, ER Positive with equal to or up to or 3 malignant lymph nodes.

Supported by:



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