

# Clinical Case Study

## Low risk patient

### Clinical Requirement

Provide clear, clinically useful, breast cancer risk recurrence guidance to assist with adjuvant therapy decision making on the requirements for either endocrine or cytotoxic therapy.

### Patient Clinical Summary



### Clinical Challenge

Traditionally a Nottingham Prognostic Index (NPI) score of 3.4 would be considered in between low and medium risk making specific risk prognosis unclear.

### Prognostic Risk Score

A **0.55** Digistain Prognostic Score measuring chromosome instability indicated a **LOW RISK** of 4% chance of developing distant metastasis based on a 10 Year Risk of Recurrence if treated with endocrine therapy alone.

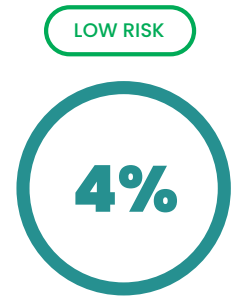
**Chart:** Shows Digistain Prognostic Score indicated where x axis curve and y axis curve meet.

**Vertical black dotted line:** Indicates the risk threshold.

**Area between dashed lines:** Indicates tolerances of Digistain Prognostic Score model.



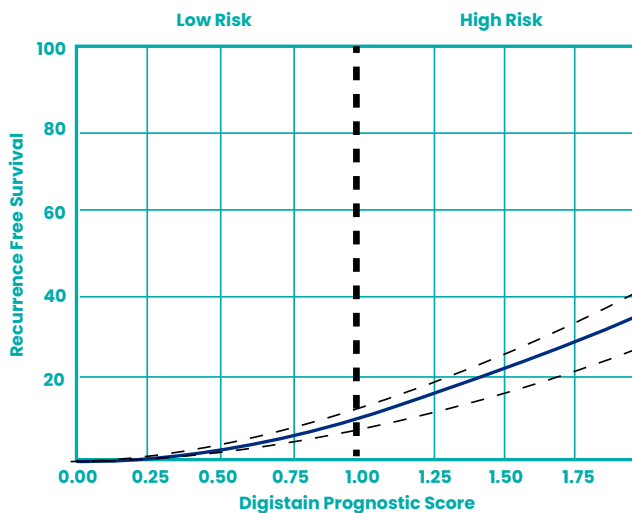
**Digistain Prognostic Score Result**



**10 Year Risk of Recurrence**  
95% CI: 3% - 5%

### Therapy Decision

The patient received systemic endocrine therapy.



### Cost/Benefit Analysis

	Traditional diagnostic test	Digistain
Time taken to conduct & return test	2-8 weeks	24-48 hours
Cost of test	-	c.75% less
Accuracy of test	High	High <sup>1</sup>

**Patient eligibility:** Digistain provides a more affordable solution that allows for borderline low/medium risk patients to benefit from a prognostic test. It is suitable for women diagnosed with invasive breast cancer who are at Stage 1 or 2, HER2 Negative, ER Positive or equal to or less than 3 malignant lymph nodes. NPI > 3.4 (medium risk).

<sup>1</sup>In 2018 Digistain undertook a clinical validation study ([link](#)) that demonstrated its technology could identify cancer recurrence risk with equivalent reliability and accuracy to gold-standard NICE-approved traditional tumour profiling Next Generation Sequencing (NGS) tests in disease-free survival and overall survival prediction, with numerically equivalent sensitivity specificity and reproducibility. The study supported Digistain's proposition that its technology can provide a cost effective way to identify low risk patients who may forego adjuvant chemotherapy that is radically faster than current methods.