# Clinical Case Study

digistain™

## 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

- Age: **62**
- Cancer type: **HER2** Negative and **ER** positive
- Tumour profile: **GRADE 2** 20 millimetres Node Negative
- NPI risk estimate: **3.4** Intermediate risk patient

### 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.

**Black dotted line:** Indicates the risk threshold.

**Blue area:** Indicates tolerances of Digistain Prognostic Score model.

**0.55**

**Digistain Prognostic Score Result**

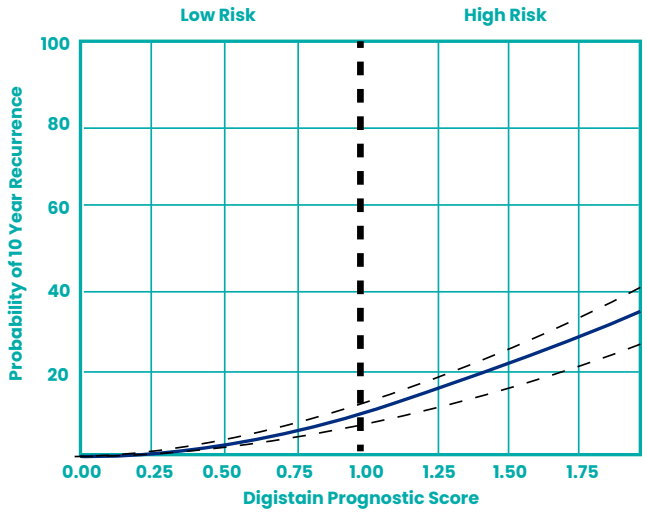
LOW RISK

**4%**

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

## Therapy Decision

The patient received endocrine FEC adjuvant therapy and responded well to treatment.




## Cost/Benefit Analysis

| | Traditional diagnostic test | Digistain |
|---|---|---|
| Time taken to conduct & return test | 2-8 weeks | 24-48 hours |
| Cost of test | [tba] | c.75% less |
| Accuracy of test | High | High[1] |

**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 < 3 malignant lymph nodes. NPI > 3.4 (medium risk).

[1]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.