

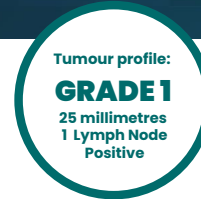
Clinical Case Study

High 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

The dilemma is that although the patient presents with a low grade tumour it has reached 1 lymph node so may fit into intermediate to high risk category. Explicit risk categorisation is required.

Prognostic Risk Score

A **1.13** Digistain Prognostic Score measuring chromosome instability indicated a **HIGH RISK** and 14% chance of developing distant metastasis based on a 10 Year Risk of Recurrence if treated with endocrine therapy alone.

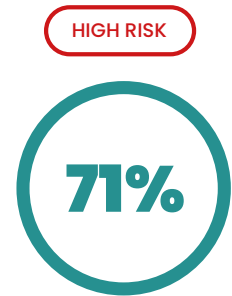
Chart: Shows Digistain Prognostic Score indicated where x axis curve and y axis curve meet.

Black dotted line: Indicates the risk threshold.

Blue area: Indicates tolerances of Digistain Prognostic Score model.



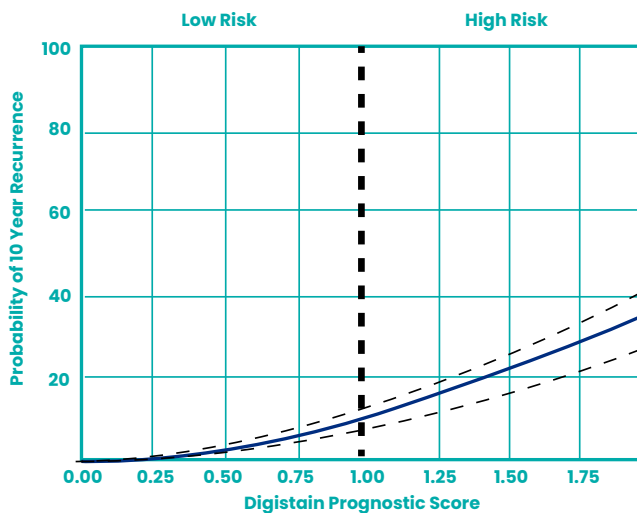
Digistain Prognostic Score Result



10 Year Risk of Recurrence
95% CI: 10% - 16%

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).

¹In 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.