Methodological quality assessment of studies investigating the MammaPrint and BluePrint tests

Study feature	Qualities sought	Stork-Sloots *et al.* (2009) (abstract)[114]
Sample of patients	Inclusion criteria defined	Y
	Sample selection explained	U
	Adequate description of diagnostic criteria	N
	Clinical and demographic characteristics fully described	N
	Representative (random or consecutive sample)	U
	Assembled at a common (usually early) point in the course of their disease	U
	Complete (all eligible patients were included)	U
Follow-up of patients	Sufficiently long	Y (5 years)
Outcome	Objective	U
	Unbiased (e.g. assessment blinded to prognostic information)	U
	Fully defined	U
	Appropriate	U
	Known for all or a high proportion of patients	U
Prognostic variable	Fully defined, including details of method of measurement if relevant	U
	Precisely measured	U
	Available for all or a high proportion of patients	U
	If relevant, cut-point(s) defined and justified	U
Analysis	Continuous predictor variable analysed appropriately	U
	Statistical adjustment for all important prognostic factors	U
Intervention subsequent to inclusion in cohort	Fully described	U
	Intervention standardised or randomised	U

N, no; U, unclear/not reported; Y, yes.

Summary of results: MammaPrint and BluePrint tests

Study	Outcomes/end points	Results	Authors' conclusions	Comments
Stork-Sloots *et al.* (2009)[114] (abstract)	Five-year survival	Profile classified: 66% (712) luminal-like; 18% (194) *ERBB2*-like; 16% (173) basal-like 13% of the samples positive for ER/PR did not express a luminal-like gene profile *ERBB2*-like or basal-like profiles showed equally poor 5-year survival rates of ~65% *ERBB2*-like subset of MammaPrint low-risk patients (15%) showed an 89% (95% CI 71% to 100%) survival rate without trastuzumab treatment Luminal-like subtypes separated into high and low risk by MammaPrint showed survival rates of 56% (95% CI 46% to 68%) for high risk and 94% (95% CI 90% to 99%) for low risk	The developed multigene profile can classify breast tumours into luminal-, *ERBB2*- and basal-like subgroups. By combining this molecular subtyping with the MammaPrint risk classification, specific groups of patients can be recognised who are at high risk of recurrence. The low-risk patients within the luminal- and *ERBB2*-like subclasses have a very low risk of recurrence. Implementation of this knowledge can improve the clinical management of breast cancer patients	