HTA Mammography Surveillance – Diagnostic Accuracy review 2

Quality Assessment Form

Version 4 **May 2010**

Study id: Extractor initials: Date:

Item		Yes	No	Unclear
1.	Was the spectrum of patients representative of the patients who will receive the test in practice? (women previously treated for primary breast cancer)			
2.	Is the reference standard likely to correctly classify the target condition?			
3a	For positive test results, is the time period between reference standard and index/comparator test short enough to be reasonably sure that the target condition did not change between the two tests? (biopsy or FNAC within 3 months, histopathology within 6 months)			
3b	For negative test results, is the time period between the index/comparator test and the reference standard short enough to be reasonably sure that the target condition did not change between the two tests? (follow-up within 3 years)			
4.	Did the whole sample or a random selection of the sample receive verification using a reference standard of diagnosis?			
5a	Did patients testing positively on the index/comparator test receive the same reference standard (i.e. FNAC or biopsy)?			
5b	Did patients testing negatively on the index/comparator test receive the same reference standard (i.e. follow up)?			
6.	Was the reference standard independent of the index test (i.e. the index test did not form part of the reference standard)?			
7.	Were the index test results interpreted without knowledge of the results of the reference standard?			
8.	Were the reference standard results interpreted without knowledge of the results of the index test?			
9.	Were index and comparator tests interpreted independently (if no record the sequence)?			
10.	Were the same clinical data available when test results were interpreted as would be available when the test is used in practice?			
11.	Were uninterpretable/intermediate test results reported?			
12.	Were withdrawals from the study explained?			

Adapted from the QUADAS Tool. Whiting et al. BMC Medical Research Methodology 2003 3:25 doi:10.1186/1471-2288-3-25