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Citation

Authors’ conclusions
Evidence from the studies examined shows that specificity and sensitivity of the BLN Assay are at least as high as conventional post-operative histology. While metastasis to the sentinel lymph nodes may be simultaneously ruled in by one test and ruled out by the other, this does not necessarily imply an erroneous result in either diagnostic method. This is a reflection of differential sampling, which may be used to advantage by undertaking the BLN Assay in tandem with post-operative histology. There is an obvious advantage in determining metastasis intra-operatively, then progressing to axillary lymph node clearance during the course of one surgical procedure rather than two. Complications and additional morbidity are avoided for the patient, while demand on health system resources is reduced. Even so, the BLN Assay has the advantage of testing more lymph node tissue on a hypothetical post-operative basis. Patients diagnosed by both histology and the BLN Assay, whether intra-operatively or post-operatively, are more likely to have an accurate result than patients examined by histology alone. Finally, an additional advantage is that the assay can be performed by trained technicians, making it more accessible than histological techniques where expert pathology is limited or under significant pressure. The BLN Assay offers a clear benefit in the role of detecting lymph node metastasis, thereby informing decisions on whether or not axillary lymph node clearance should be performed. The assay has high potential for complementing conventional histology for improved diagnosis on the basis of more extensive examination of lymph node tissue. Furthermore, the ability to avoid additional costs and morbidity associated with axillary lymph node dissection during a second procedure add to the advantages seen in the performance of this technology. However, during the preparation of this update for publishing, it was discovered that the manufacturer has withdrawn the BLN Assay. Therefore, no further review of this technology by HealthPACT is warranted.

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