

OSNA

Accurate, quantitative molecular diagnostics adds value to nodal staging in breast cancer

Axillary lymph node (ALN) status is still one of the most important prognostic factors for patients with breast cancer. As a result, an accurate and standardised determination of metastatic nodal burden within the ALN is of utmost importance when selecting the correct treatment, thus avoiding over- as well as under-treatment.

Molecular analysis of sentinel lymph nodes (SLN) by quantification of CK19 mRNA expression with OSNA has shown to provide more differentiated diagnostic information compared to conventional histopathology.

During the last years, the clinical evidence gained by OSNA has evolved during a period of change in axillary management from merely determining the size of the metastasis to a quantitative determination of nodal burden for a personalised approach.

OSNA adds value to nodal staging since it not only provides information about the presence or size of nodal metastasis, but offers valuable predictive and prognostic information for guiding treatment decisions (Fig. 1). This can help to decide whether patients can be safely spared axillary lymph node dissection (ALND), what kind of adjuvant therapy might be needed and to select the appropriate radiotherapy regimen.

OSNA molecular cut-offs for clinical decision-making

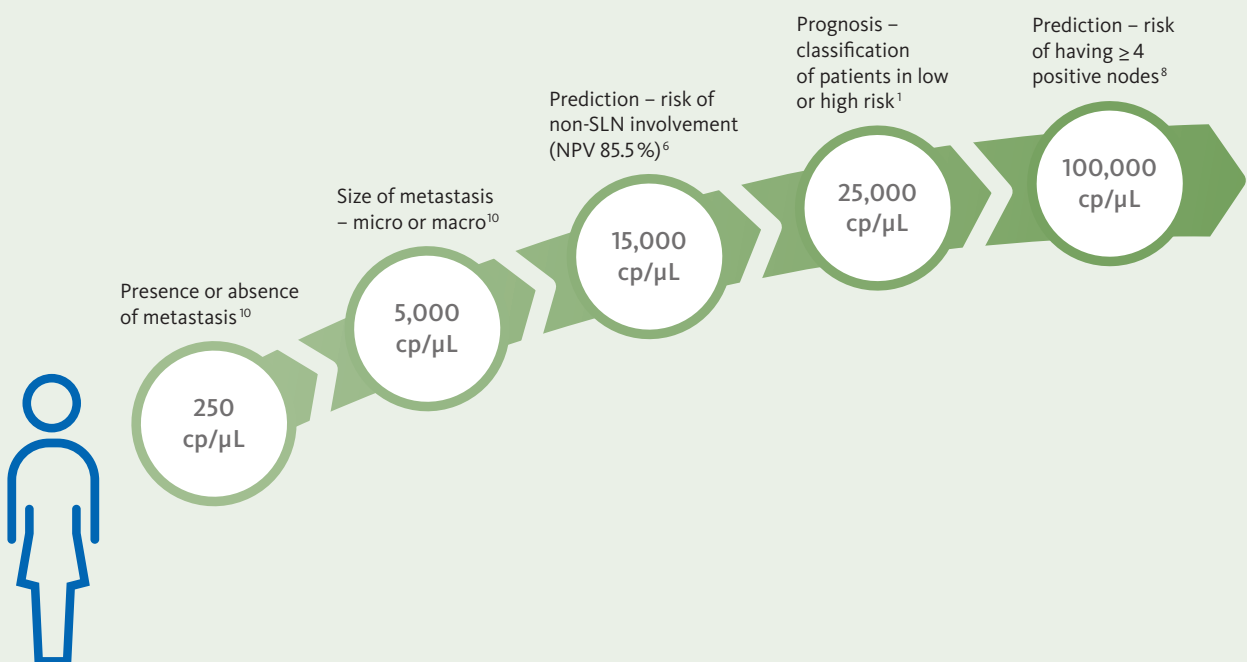


Figure 1: Overview of OSNA molecular cut-offs. Abbreviation cp/μL corresponds to copies/μL of CK19 mRNA.

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Selected publications

- [1] **Peg V et al. (2017):** Role of total tumour load of sentinel lymph node on survival in early breast cancer patients. *Breast*. 33:8 – 13.

Key message: The total tumour load in the SLN determined by OSNA allows to distinguish between two patient groups in terms of DFS and OS, independently of axillary staging (pN), age and tumour characteristics.



- [2] **Fung V et al. (2017):** Intraoperative prediction of the two axillary lymph node macrometastases threshold in patients with breast cancer using a one-step nucleic acid cytochrome-19 amplification assay. *Mol Clin Oncol*. 7(5):755 – 762.

Key message: OSNA identifies a total tumour load cut-off value where dissection of ALN may be avoided in patients with SLN positivity.

- [3] **Aristei C et al. (2016):** The 2016 Assisi Think Tank Meeting on breast cancer: white paper. *Breast Cancer Res Treat*. 160(2):211 – 221.

Key message: Several ongoing studies are investigating the axillary treatment including regional lymph node RT. The OPTIMAL trial evaluates early-stage breast cancer patients with SLN assessed by OSNA: incidental versus intentional RT to level I–IV nodes.



- [4] **Di Filippo F et al. (2016):** Elaboration of a nomogram to predict non-sentinel node status in breast cancer patients with positive sentinel node, intraoperatively assessed with one-step nucleic amplification: Retrospective and validation phase. *J Exp Clin Cancer Res*. 35(1):193.

Key message: The OSNA nomogram supports surgeons in choosing the right treatment during the operation and avoids for the patient a second surgery procedure.

- [5] **Rubio IT et al. (2014):** Nomogram including the total tumoral load in the sentinel nodes assessed by one-step nucleic acid amplification as a new factor for predicting non-sentinel lymph node metastasis in breast cancer patients. *Breast Cancer Res Treat*. 147(2):371 – 380.

Key message: The nomogram incorporates the total tumour load assessed by OSNA. It is a useful tool to predict non-SLN positivity and support clinicians in decision-making.



- [6] **Peg V et al. (2013):** Intraoperative molecular analysis of total tumor load in sentinel lymph node: a new predictor of axillary status in early breast cancer patients. *Breast Cancer Res Treat*. 139(1):87 – 93.

Key message: The total tumour load determined by OSNA predicts the axillary nodal status independently of the number of affected lymph nodes and the type of surgery, thus better supporting clinicians in personalising surgical treatment.

- [7] **Osako T et al. (2013):** Sentinel node tumour burden quantified based on cytochrome 19 mRNA copy number predicts non-sentinel node metastases in breast cancer: Molecular whole-node analysis of all removed nodes. *Eur J Cancer*. 49(6):1187 – 95.

Key message: The CK19 mRNA copy number determined by OSNA predicts non-SLN metastases. This study further supports the predictive value of the OSNA result.



- [8] **Ohi Y et al. (2012):** Whole sentinel lymph node analysis by a molecular assay predicts axillary node status in breast cancer. *Br J Cancer*. 107(8):1239 – 43.

Key message: Analysis of the whole SLN by the OSNA assay could become a valuable approach for predicting the presence of metastases in four or more ALN.

- [9] **Bernet VL et al. (2011):** Molecular diagnosis of sentinel lymph nodes for breast cancer: one step ahead for standardization. *Diagn Mol Pathol*. 20(1):18 – 21.

Key message: OSNA is a very sensitive, specific and reproducible method that enables standardisation of the SLN diagnostic procedure.



- [10] **Tsujimoto M et al. (2007):** One-step nucleic acid amplification for intraoperative detection of lymph node metastasis in breast cancer patients. *Clin Can Res*. 13:4807 – 16.

Key message: The OSNA assay provides similar results to those of three-level histopathology and it is a useful approach for the intraoperative detection of lymph node metastasis in breast cancer patients.

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