

**PUBLICATION SPOTLIGHT**

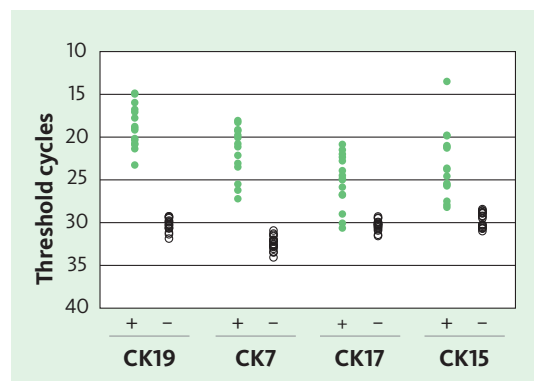
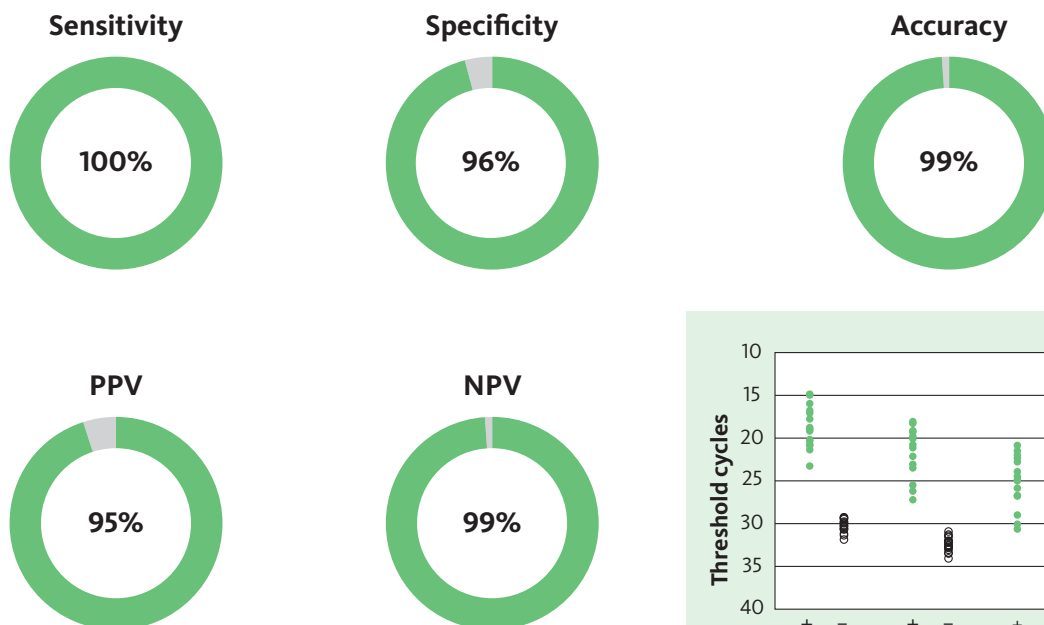
## OSNA

# Molecular nodal staging in lung cancer

In lung cancer, nodal status not only supports treatment decisions but is also a key prognostic factor since the presence of lymph node (LN) metastases is associated with worse survival rates. Disease-free survival (DFS) in resectable non-small cell lung cancer (NSCLC) decreases dramatically from 83.2% in N0 to 6.5% in N3 patients\*. Not surprisingly, occult metastases have been associated with a significantly worse DFS (hazard ratio [HR], 1.50) and overall survival (HR, 1.58)\*\*. Metastases may remain undetected by conventional histology since it only analyses a small portion of the node.

In contrast, OSNA provides a fast and whole node analysis for the most common subtypes of NSCLC (e.g. adenocarcinomas and squamous cell carcinomas). It can be applied in the intra- as well as post-operative setting. OSNA detects metastases regardless of their size or location in the node, thus providing a more accurate diagnosis and with this prognosis, enabling the right treatment choice to be made for the patients. Vodicka et al. showed that thanks to OSNA, 22% of patients were upstaged<sup>2</sup> where conventional histology was not sensitive enough.

OSNA offers a molecular analysis by quantifying the expression of CK19 mRNA in the LN, reflecting the presence or absence of metastasis. Among 16 mRNA markers with high expression in lung cancer, CK19 reported the best performance to detect LN metastases<sup>7</sup>. A strong correlation of the CK19 expression was observed between the primary tumour and the LN metastasis<sup>5</sup> in adenocarcinomas and squamous cell carcinomas. OSNA has been compared to histopathological examination in more than 2,400 LNs<sup>1-7</sup>, where each node was analysed by both methods achieving highly favourable results.



\* Wei et al. (2011). J Thorac Oncol. 6(2):310-8.

\*\* Rusch et al. (2011). J Clin Oncol. 10;29(32):4313-9.

● Histopathologically negative LN  
○ Histopathologically positive LN

# OSNA – Molecular analysis of lymph node metastases to support treatment decisions in lung cancer

## Publications

[1] **Pérez et al. (2019):** Detection of lymph node metastasis in lung cancer patients using a one-step nucleic acid amplification assay: a single-centre prospective study. *J Transl Med.* 17:233. [abstract]

**Key message:** The high sensitivity of OSNA enables detection of tumour cells missed by pathological examinations. These occult metastases may be the key to explain why some patients staged pNO or pN1 after surgery are progressing with worse prognosis.



[2] **Vodicka et al. (2018):** A more sensitive detection of micrometastases of NSCLC in lymph nodes using the one-step acid amplification (OSNA) method. *J Surg Oncol.* 117(2):163-170. [abstract]

**Key message:** OSNA has shown to be more sensitive by detecting more tumor cells in comparison with both H&E and IHC CK19, resulting in a higher pTNM stage in 22% of patients.

[3] **Nakagawa et al. (2016):** The novel one-step nucleic amplification (OSNA) assay for the diagnosis of lymph node metastasis in patients with non-small cell lung cancer (NSCLC): results of a multicentre prospective study. *Lung Cancer.* 97:1-7. [abstract]

**Key message:** OSNA has shown to be equivalent to the 3-level histological examination and can improve the detection of metastases by analyzing the whole lymph node.



[4] **Oezkan et al. (2016):** OSNA: A fast molecular test based on CK19 mRNA concentration for assessment of EBUS-TBNA samples in lung cancer patient. *Clinical Lung Cancer.* 17(3):198-204. [abstract]

**Key message:** The OSNA analysis can be completed within 16 minutes per sample. OSNA is an advantageous method for quick and accurate detection of lymph node metastases, thus suitable for intra-operative use.

[5] **Masai et al. (2014):** Cytokeratin 19 expression in primary thoracic tumors and lymph node metastases. *Lung Cancer.* 86(3): 318-23. [abstract]

**Key message:** Most thoracic tumors express CK19 and the expression in CK19-positive primary tumour was maintained in the corresponding LN metastasis.



[6] **Hayama et al. (2014):** One-step nucleic acid amplification for detection of lymph node metastasis in lung cancer. *Ann Thorac Cardiovasc Surg.* 20(3): 181-4. [abstract]

**Key message:** OSNA can successfully detect lymph node metastasis in lung cancer, which was confirmed by conventional histopathology. The sensitivity of OSNA was 100.0% and its specificity was 91.7%.

[7] **Inoue et al. (2012):** An accurate and rapid detection of lymph node metastasis in non-small cell lung cancer patients based on one-step nucleic acid amplification assay. *Lung Cancer.* 78(3): 212-8. [abstract]

**Key message:** Among 16 target markers with high expression in lung carcinoma, CK19 reported the best performance for the detection of nodal metastases. Additionally, OSNA is a promising rapid method for intraoperative diagnosis required for the use of less invasive surgical procedures, such as sublobar resection.



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