



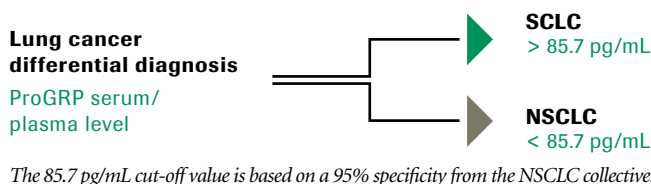
Elecsys[®] ProGRP assay
*Decisive information for the differential
diagnosis in lung cancer*



Elecsys® ProGRP assay

Decisive information for the differential diagnosis in lung cancer

Lung cancer is one of the most common cancers in the world with 1.35 million new cases diagnosed every year. This represents approximately 13% of all new cancers. It is also one of the most common causes of death from cancer.¹ The two main histological types of the disease are small cell lung cancer (SCLC) and non-small cell lung cancer (NSCLC). It is important to distinguish between these two subtypes as they have different treatments and prognoses. NSCLC (approx. 80% of cases), when in early stages, is curable with surgery. SCLC, however, is an aggressively spreading neoplasm of rapid growth that is treated with chemo- and radiotherapy.^{2,3,4}



ProGRP – the marker of choice for SCLC

- High discrimination between SCLC and NSCLC/other malignancies/benign diseases (figure 1)⁵
- Highest sensitivity for SCLC as compared to other lung cancer tumor markers. Further increase in sensitivity when combined with NSE⁶
- Recommended by the NACB for differential diagnosis, post-operative surveillance, monitoring therapy in advanced disease, and detection of recurrent disease⁷

Leading ECL technology for best-in-class performance

- Higher sensitivity and specificity for better discrimination between SCLC and NSCLC (table 1)
- Excellent precision across the entire measuring range for reliable results
- Equivalent performance between serum and plasma (figure 2) allowing ProGRP and NSE to be tested out of one tube (NSE is not suitable for use with plasma due to nature of analyte)

Increased efficiency and result consistency

- Lung cancer testing all on one automated platform – CEA, CYFRA 21-1, NSE, and ProGRP
- Consolidation with the leading and committed portfolio of tumor markers from Roche – PSA, fPSA, Ferritin, HCB+β, AFP, Calcitonin, Tg, CA19-9, CA125, CA15-3, CA72-4, S100, HE4
- Consistent results across cobas SWA platforms – automated platforms for every lab size

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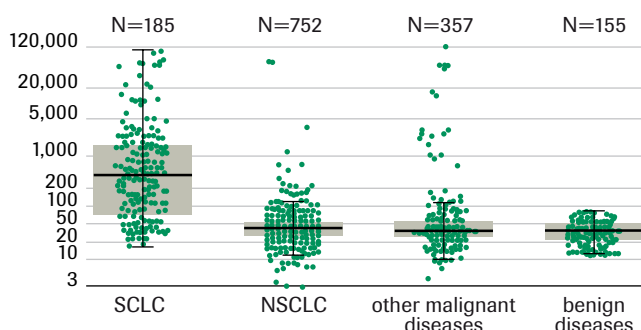


Figure 1: Other malignant diseases include breast, ovary, prostate, renal, liver, pancreas, colorectal, gastrointestinal, carcinoid, cervical, medullary carcinoma of the thyroid, mesothelioma, neuroendocrine tumors, lymphoma, and stomach cancer. Benign diseases contain liver-, metabolic-, autoimmune- and inflammatory diseases, as well as the benign lung diseases of pneumonia, asthma, chronic obstructive pulmonary disease, and tuberculosis.

	Elecsys® ProGRP assay ⁵ (cut-off: 85.7 pg/mL)	Abbott ARCHITECT ProGRP Assay* (cut-off: 70 pg/mL)
Sensitivity	72.4%	59%
Specificity	95%	92%

Table 1: Sensitivity is calculated as the percentage of individuals with SCLC with whom the tests gives an SCLC-positive result (result > cut-off). Specificity is calculated as the percentage of individuals with NSCLC with whom the test gives an NSCLC-positive (result < cut-off). *Calculated from Abbott ARCHITECT ProGRP assay package insert (2008) data.

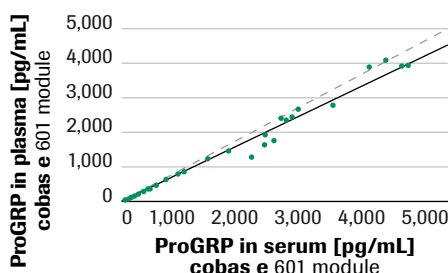


Figure 2:
P/B regression
 $Y = 0.908 * X - 1.03$
 $md(95) = 153.891$
 $N = 169$ $r = 0.9959$
 $t = 0.9578$

References

- 1 Globocan Database: [http:// globocan.iarc.fr/](http://globocan.iarc.fr/)
- 2 Spira, A., Ettinger, D.S. (2004). Multidisciplinary management of lung cancer. *N Engl J Med.* 350, 379–392
- 3 Schiller, J.H. (2001). Current standards of care in small-cell and non-small-cell lung cancer. *Oncology.* 61, 3–13
- 4 Stupp, R., Monnerat, et al. (2004). Small cell lung cancer: state of the art and future perspectives. *Lung Cancer.* 45, 105–117.
- 5 Roche study No. RD001525 and RD000788
- 6 Shibayama, T., Ueoka, H., Nishii, K., et al. (2001). Complementary roles of pro-gastrin-releasing peptide (ProGRP) and neuron specific enolase (NSE) in diagnosis and prognosis of small cell lung cancer (SCLC). *Lung cancer.* 32, 61 – 69.
- 7 Stieber, P., Hatz, R., et al. National Academy of Clinical Biochemistry Guidelines for the Use of Tumor Markers in Lung Cancer. NACB: Practice Guidelines And Recommendations For Use Of Tumor Markers In The Clinic, *Lung Cancer (Section 3P)*.