



MonoTotal®

For high sensitivity in NSCLC

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MonoTotal® is a sensitive tumor activity marker for detection and identification of Non-Small Cell Lung Cancer (NSCLC). By using **MonoTotal®**, the physician can get an early indication of the course of the disease, measured in terms of tumor cell activity instead of more conventional tumor burden measurements. **MonoTotal®** provides the physician with a helpful aid in diagnosis, prognosis and monitoring of the disease.

Background lung cancer

Lung cancer is the most frequently diagnosed cancer and the leading cause of death by cancer worldwide. It kills more people than colon, breast and prostate combined (WHO statistics). Lung cancer has different histological types and these are distinguished in two sub-types, small-cell lung cancer (SCLC) and non-small cell lung cancer (NSCLC). Approximately 80-85% of lung cancer patients are of NSCLC, SCLC accounts for about 15-20% of new lung cancer cases. One effective treatment for early stage NSCLC is surgical resection, however the majority of the patients present with advanced and inoperable disease. Approximately 15-20% of the lung cancer patients are diagnosed when the disease is still restricted to the lungs and early detection is critical to increase the chances of survival.

Tumor markers, alone or in combination have been investigated for their value in lung cancer. The most common biomarkers found to be of clinical significance in lung cancer are CEA, CYFRA 21-1, TPA, TPS, NSE and ProGRP. However, the lack of sensitivity and specificity limits the use of cancer biomarkers for screening and early diagnosis of lung cancer. For the prognostic evaluation and monitoring the course of the disease the cancer biomarkers appears to be more effective.

Cytokeratin filaments

All eukaryotic cells have cytoplasmatic cytoskeletal structures known as intermediate filaments. The cytoskeletal network is responsible for the mechanical integrity of the cell and it is critical during cellular processes like cell division, motility and cell to cell contacts. At present more than 20 different cytokeratins have been identified, of which cytokeratin 8, 18 and 19 are the most abundant in simple epithelial cells. The cytokeratins are epithelial cell specific and the cytokeratin pattern is usually preserved during the transformation of normal cells into malignant cells.

MonoTotal®

MonoTotal® is a quantitative immunoassay that specifically measures defined epitopes especially on cytokeratin 19 but also 8 and 18. The test result is directly proportional to the concentration of soluble cytokeratin fragments in serum. An elevated level of soluble cytokeratin fragments in patient samples is an indication of epithelial tumor cell activity.

Product	Catalogue number	
MonoTotal® ELISA	10-027	Assay time less than 3 hours
MonoTotal® IRMA	10-028	Assay time less than 3 hours

MonoTotal® for efficient management in lung cancer

MonoTotal® correlates well with tumor cell activity and the extent of the disease. Studies published during the last years shows that **MonoTotal®** has a strong association with clinical response in patients. **MonoTotal®** demonstrates high sensitivity in patients with NSCLC, independent of histotype. The overall sensitivity is about 70-75%, at 95% specificity and correlates well with tumor cell activity and the extent of the disease.

MonoTotal® sensitivity in non-small cell lung cancer (NSCLC) patients (stages Ia-IIIb)

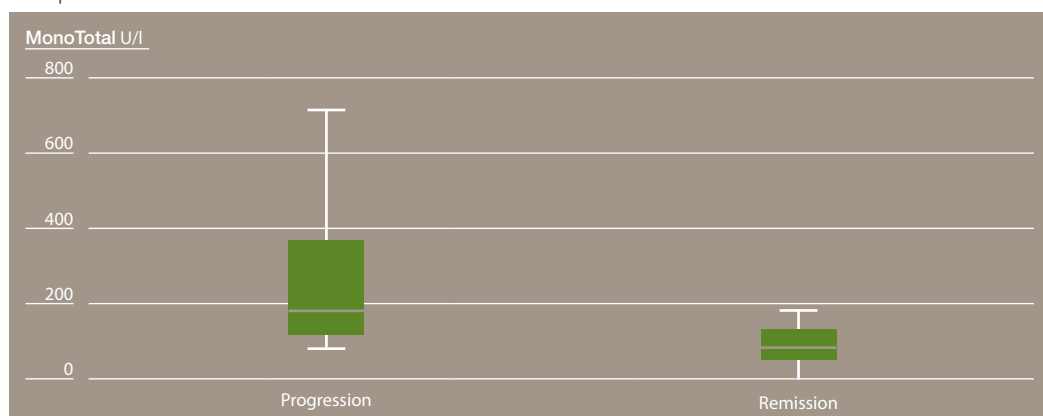
Tumor Marker	Sensitivity (95% specificity)	ROC-analysis – AUC (Area Under Curve)
MonoTotal®	71%	0.895
CYFRA 21-1	51%	0,802
TPA	53%	0,751

Number of patients: 69 NSCLC patients (stages Ia-IIIb, 20 adenocarcinoma, 49 squamous cell carcinoma)
Data from Holubec et al. 2008

MonoTotal® levels relates to remission and progression during follow-up

MonoTotal® predicts clinical outcome (disease free interval and overall survival) and is an early indicator of relapse during follow up in NSCLC. Increase in **MonoTotal®** values often precede detection of relapse by conventional image methods.

The difference in post-surgery levels of **MonoTotal®** was shown in a study from 2011. The figures demonstrate a significantly higher **MonoTotal®** level in NSCLC patients with progression compared to those with remission.



Number of patients: 93 patients with newly diagnosed NSCLC who had undergone lung surgery.
Data from Prazakova et al. 2011

At a glance

MonoTotal® - For high sensitivity in NSCLC

- **MonoTotal®** is a tumor marker measuring the cytokeratins 19, 8 and 18 in serum
- **MonoTotal®** is an indicator of tumor cell activity which provides the clinician with early signals about disease course
- **MonoTotal®** demonstrates high diagnostic sensitivity for non-small cell lung cancer (NSCLC)
- **MonoTotal®** is an aid in monitoring disease progression during the course of disease and treatment outcome
- **MonoTotal®** levels decrease in response to successful treatment
- Increased **MonoTotal®** levels during follow up may indicate relapse

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Diagnostic tools for reliable patient management.

Oncology

TPS® UBC® TPAcyk™ MonoTotal®

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