



ichromaTM Cyfra21-1

Sensitive and specific tumor marker of non-small cell lung cancer (NSCLC)

- Quantitative fluorescence immunoassay
- Fast test result in 12 min with small sample volume
- Easier to handle and storage stable

Cyfra21-1 test benefits

Cyfra21-1 is a sensitive and valuable biomarker for estimation of diagnosis, prognosis, and therapy monitoring of lung cancer and Boditech Med provides diverse tumor marker panel to improve the diagnostic accuracy.



What is Cyfra21-1 test?

- Cyfra21-1 (Cytokeratin 19 fragment) belongs to a cytokeratin family, which is normally expressed throughout body fluids
- Can be used as circulating tumor marker as it is a serum-soluble antigen
- Mainly occurs in the lung, particularly in lung cancer tissues
- Can be elevated in other cancers, such as bladder, lung, breast cancers
- Although associated with small cell and NSCLC, it is most sensitive for NSCLC, primarily squamous cell carcinoma

Clinical Usefulness

- Lung cancer is by far the leading cause of cancer death ; over than half of people with lung cancer die within one year of being diagnosed and the 5-year survival rate in advanced-stage is 15%, as compared to 80% in early-stage
- Early detection and diagnosis is urgent for the sake of an effective treatment strategy for lung cancer
- Cyfra21-1 reflects the extent of the disease and proved to be sensitive and valuable biomarkers for estimation of diagnosis, prognosis, and therapy monitoring of lung cancer

ichroma™ Cyfra21-1 Specification

ichroma™ Cyfra21-1 is a fluorescence immunoassay (FIA) for the quantitative determination of circulating Cyfra21-1 in blood.

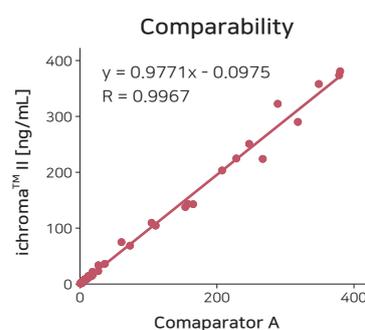
Test principle	Fluorescence Immunoassay (FIA)
Sample type	Serum, plasma
Sample volume	10 µL
Assay time	12 min
Reference value	3.3 ng/mL
Working range	1-500 ng/mL
Storage and shelf life	Up to 20 months at 2-30 °C
Available platform	ichroma™ II, ichroma™ III, ichroma™ M2

Ordering information

Product	Cat. No.
ichroma™ Cyfra21-1	CFPC-140
ichroma™ Cyfra21-1 Control	CFPC-357
ichroma™ II	FPRR021
ichroma™ III	FPRR037
ichroma™ M2	FPRR031

Performance

ichroma™ Cyfra21-1 showed equivalent and comparable test result compared with laboratory device.



References

- 1) Gayo, Sonsoles Garcia-Valdecasas, et al. "CYFRA 21-1 in patients with suspected cancer: evaluation of an optimal cutoff to assess the diagnostic efficacy and prognostic value." *Advances in Laboratory Medicine/Avances en Medicina de Laboratorio* 1.4 (2020).
- 2) Wieskopf, Bram, et al. "Cyfra 21-1 as a biologic marker of non-small cell lung cancer: evaluation of sensitivity, specificity, and prognostic role." *Chest* 108.1 (1995): 163-169.
- 3) Sokoll, Lori J., and Daniel W. Chan. "Tumor markers." *Contemporary Practice in Clinical Chemistry*. Academic Press, 2020. 779-793.
- 4) Biaoxue, Rong, et al. "Differential diagnostic CYFRA 21-1 level for benign and malignant pleural effusions: a meta-analysis in the Chinese population." *Archives of Medical Science* 8.5 (2012): 756-766.
- 5) Zhang, Li, et al. "The important role of circulating CYFRA21-1 in metastasis diagnosis and prognostic value compared with carcinoembryonic antigen and neuron-specific enolase in lung cancer patients." *BMC cancer* 17.1 (2017): 1-14.
- 6) Fu, Lei, et al. "CYFRA21-1 tests in the diagnosis of non-small cell lung cancer: a meta-analysis." *The International Journal of Biological Markers* 34.3 (2019): 251-261.
- 7) Hoseok, I., and Je-Yoel Cho. "Lung cancer biomarkers." *Advances in clinical chemistry* 72 (2015): 107-170.