BioVendor R&D®

KL-6

Superior Marker of Interstitial Lung Disease

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Krebs von den Lungen-6 (KL-6)

Serum KL-6 is the most sensitive and specific **serum marker of interstitial lung disease (ILD)**, the release of KL-6 results from alveolar epithelial cell damage and destruction, a recent meta-analysis observed KL-6 diagnostic sensitivity (0.85, 95% CI, 0.77–0.91) and specificity (0.97, 95% CI, 0.90–0.99) for interstitial lung disease.

KL-6 levels reflect the severity of interstitial lung disease associated with **fibrosing progression** of the disease.

KL-6 levels are associated with the presence of connective tissue disease in ILD-related autoimmune diseases: rheumatic arthritis, inflammatory myositis, Sjoengren's syndrome or systemic lupus erythermatosus (SLE).

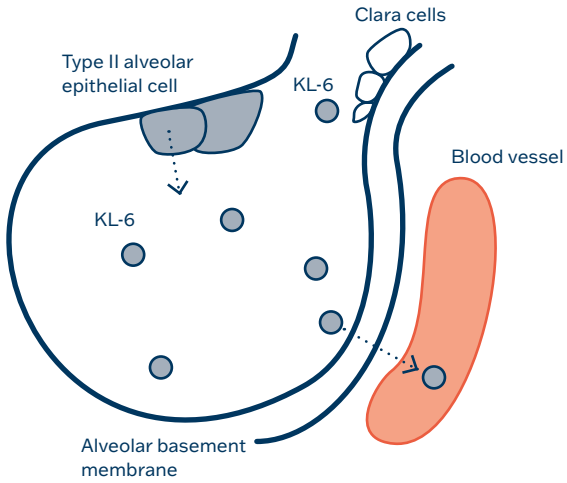
Changes in serum KL-6 predict **the mortality** for patients with **acute exacerbation in interstitial lung disease**, and for patients with IPF.

Background

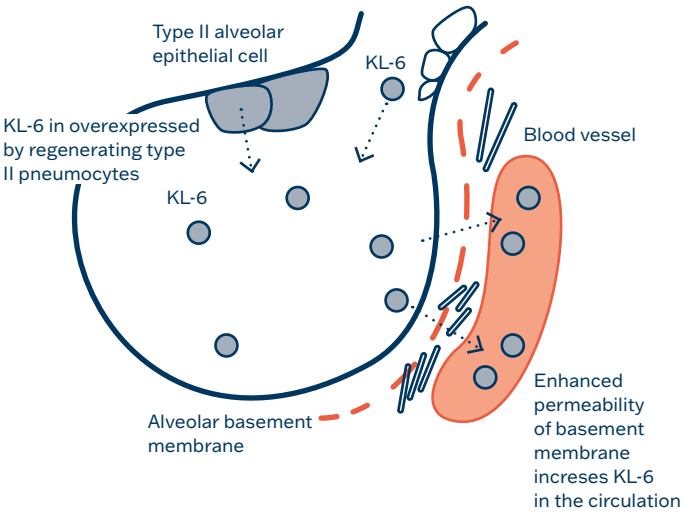
Krebs von den Lungen-6 (KL-6) is a high-molecular mucin-like glycoprotein, encoded by MUC1 gene. KL-6/MUC1 regulates cell-cell interactions and shows also chemotactic activity. It is distributed mainly on the cell surface of type II alveolar epithelial cells (AECs). During the inflammatory storm, the disulfide bonds on the surface of the epithelial cell membrane may be damaged and KL-6 released into the pulmonary epithelia lining fluid and blood circulation. Increased levels of KL-6 in patients with IPF are due to higher production of KL-6 by regenerating alveolar type II pneumocytes and by its increased release following alveolar damage in the affected lung.

Reference: Ishikawa N, Hattori N, Yokoyama A, Kohno N. Utility of KL-6/MUC1 in the clinical management of interstitial lung diseases. Respir Investig. 2012 Mar;50(1):3-13. doi: 10.1016/j.resinv.2012.02.001. Epub 2012 Mar 8. PMID: 22554854.

Normal lung



Affected lung



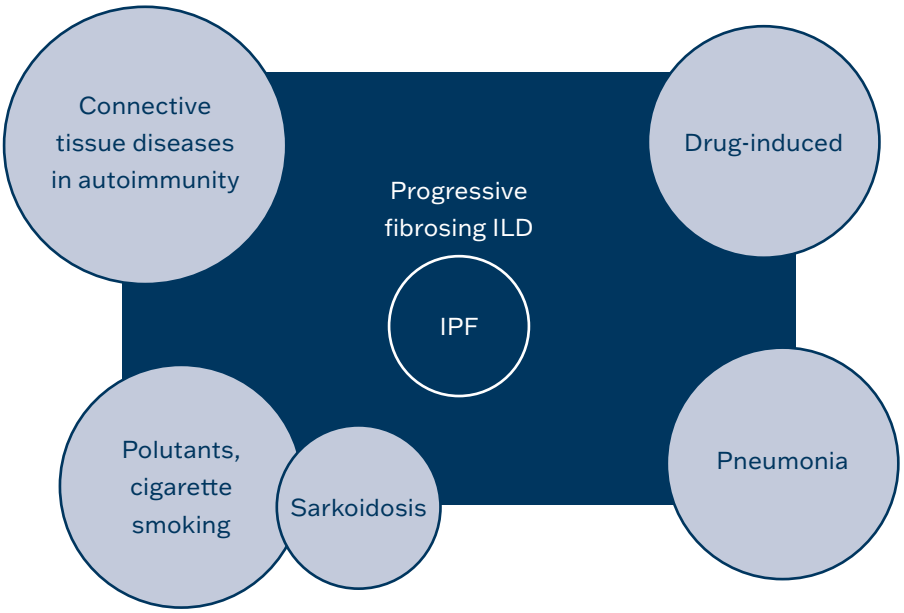
Presence of KL-6 in the lungs

KL-6 is mildly presented in the type II pneumocytes and respiratory bronchiolar epithelial cells and weakly in the basal cells of the bronchiolar epithelium of healthy lungs. No KL-6 expression was observed on type I pneumocytes, goblet cells and mucous cells of the bronchial glands. KL-6 is strongly expressed by the altered and/or regenerating type II pneumocytes in tissue sections obtained from the patients with IPF.

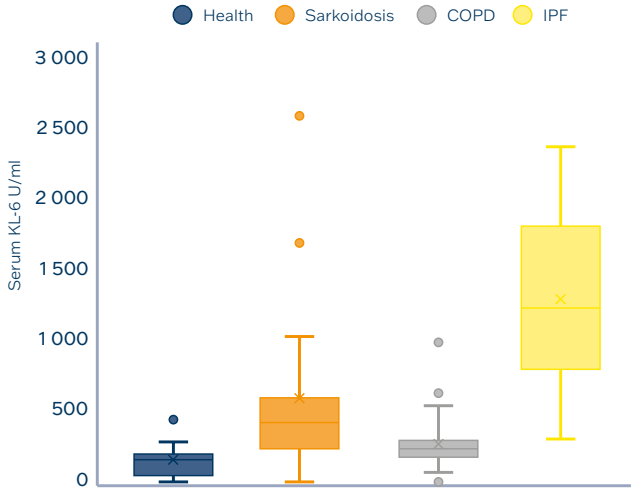
KL-6 and Interstitial Lung Disease: Diagnosis and disease activity

Interstitial lung disease (ILD) represents a range of heterogeneous difussed parenchymal disorders often characterized by fibrosis of the lungs at advanced stages, and effecting the alveolar space and pulmonary interstitium. Interstitial Pulmonary Fibrosis (IPF) is one of ILDs, that is caused by the loss of function of alveoli, bronchioles and pulmonary interstitium, and its scarring resulting in the decrease of lung capacity. IPF represents progressive fibrosing ILD, which could develop also in the other ILDs. The swiftness of treatment and the disease activity are vital for good patient prognosis. Increased serum levels of KL-6 in ILD patients were shown in many clinical studies. The comparison of serum KL-6 levels determined with BioVendor's Human KL-6 ELISA kit reports typical serum KL-6 levels in healthy individuals, patients with sarcoidosis, COPD and IPF (in-house data).

Interstitial Lung Disease (ILD)

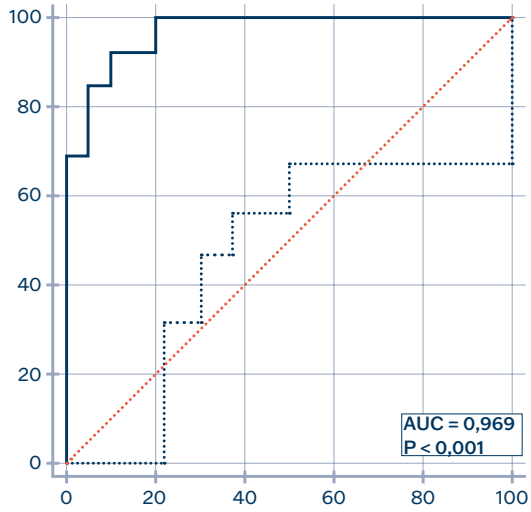


BioVendor Human KL-6 ELISA



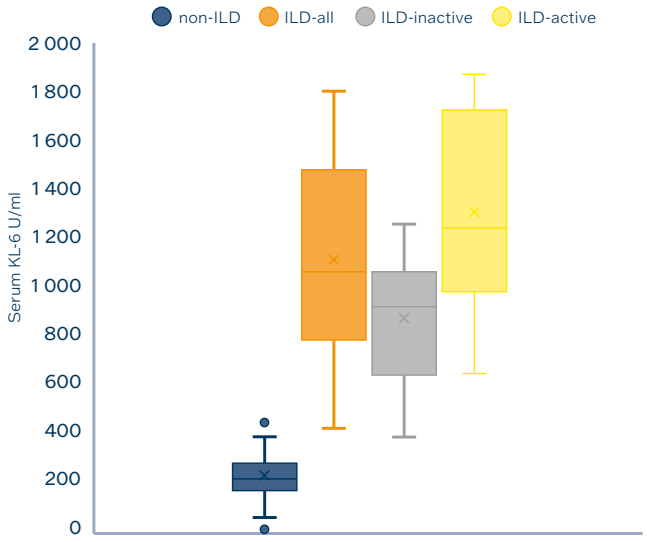
Risk serum KL-6 values: over 250 U/ml (95percentil of healthy individuals). Determined with BioVendor's Human KL-6 ELISA, Cat. No. RBL004R.

ROC Analysis: Serum KL-6



ROC analysis COPD vs IPF: cut-off 385 U/ml, clinical specificity 90%, clinical sensitivity 92,3 %, AUC 0,969, 95% confidence interval 0,842 to 0,999 (— serum KL-6). Determined with BioVendor's Human KL-6 ELISA, Cat. No. RBL004R.

Interstitial Lung Disease activity assessment



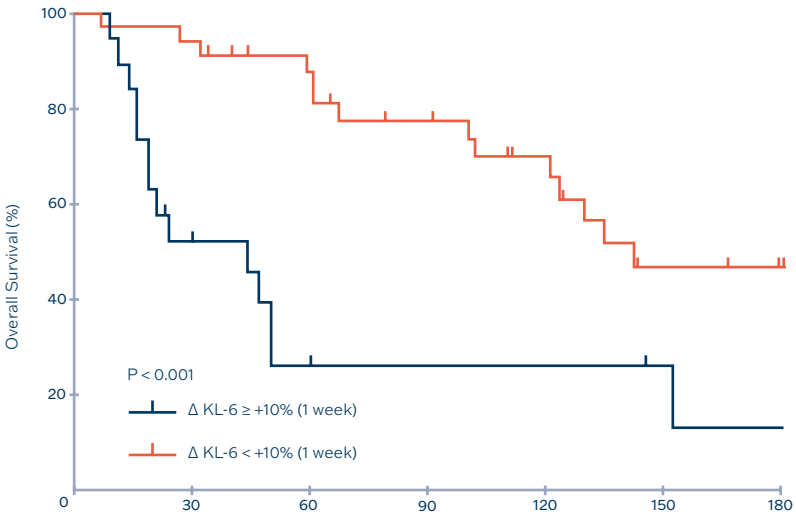
Over differentiation among various ILDs, the challenge is the identification of individuals with extensive lung fibrosis, and progressive fibrosing ILD respectively. The study from He et al. referred comparison among non-Interstitial Lung Disease (non-ILD), Interstitial Lung Disease (ILD-all), and separately non-progressive fibrosing ILD (ILD-inactive) against progressive fibrosing ILD (ILD-active).

Reference: He Q, Tang Y, Huang J, Rao Y, Lu Y. The value of KL-6 in the diagnosis and assessment of interstitial lung disease. Am J Transl Res. 2021 Aug 15;13(8):9216-9223. PMID: 34540037; PMCID: PMC8430136.

KL-6 and Interstitial Lung Disease: Mortality in patients with acute exacerbation

The changes in blood KL-6 levels within 1 week hospitalisation were higher in non-survivals. Patients with remarkable increase in KL-6 (≥10%) showed significantly worse survival (in-hospital mortality: 63.2 vs. 6.1%, median survival: 42 vs. 142 days; P<0.001) than those without.

Reference: Choi, M.G., Choi, S.M., Lee, J.H. et al. Changes in blood Krebs von den Lungen-6 predict the mortality of patients with acute exacerbation of interstitial lung disease. Sci Rep 12, article 4916 (2022). PMID: 35318424 https://doi.org/10.1038/s41598-022-08965-9



Human KL-6 ELISA

Cat.No.	RBL004R
Size	96 wells
Assay type	sandwich ELISA, employing MAb as capture and MAb-biotin as detector
Regulatory status	RUO
Validated for serum, plasma and BALF; recommended sample dilution	serum, plasma and BALF; 200x
Assay time	less than 3hours
Serum Quality Control A, Serum Quality Control B	
Measuring range	0.156–10 U/ml
Sensitivity	0.04 U/ml
Serum/ plasma normal value	0–250 U/ml
Cut-off value of serum KL-6 between COPD and IPF	385 U/ml

Related products

Product	Cat. No.	Regulatory Status
Human ACE2 ELISA	RAG006R	RUO
Human Club Cell Protein (CC16) ELISA	RD191022200	CE IVD
Human Connective Tissue Growth Factor ELISA	RD191035200R	RUO
Human Interleukin-6 ELISA	RD194015200R	CE IVD
Human MMP-2 ELISA	RBL001R	RUO
Human MMP-3 ELISA	RBL003R	RUO
Human MMP-9 ELISA	RBL002R	RUO
Human S100A12 ELISA	RD191221200R	RUO
Human Soluble Mannose Receptor ELISA	RHK381-01R	RUO
Human Soluble Receptor for Advanced Glycation End Products (sRAGE) ELISA	RD191116200R	RUO
Human Surfactant Protein D ELISA	RD194059101	CE IVD

CE IVD The kits are CE-IVD certified and intended for professional use.

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