

- **Heart Failure (HF)** is a chronic, progressive condition in which the heart muscle is unable to pump sufficient quantity of blood through the arterial system.
- **Myocardial fibrosis**, characterized by alterations in the quantity and quality of the collagen network, is involved in the development and progression of HF.
- There is an unmet **need** to identify inadequately-treated, high risk HF patients with alterations in collagen type I quantity (CD) and cross-linking (CCL) leading to the development of fibrosis.
- A **panel of biomarkers**, measurable in blood, has been identified and validated for identifying alterations in CD and CCL, useful for risk stratification, personalized therapy and monitoring of therapy effectiveness in patients with HF.
- **Primary Indication:** Heart Failure.

Scope of the problem

- In the US, over 5.7 million people are currently living with HF. An estimated 400,000 to 700,000 new cases of HF are diagnosed each year.
- About half of people who develop HF die within 5 years of diagnosis. HF is the cause for 12-15 million medical visits per year and 6.5-7 million days of hospitalization per year.
- Myocardial fibrosis is an independent predictor of mortality and morbidity in HF patients.

Patient need addressed

Noninvasive techniques that can quickly identify the alterations in the collagen network.

Panel of Biomarkers

- PICP: Index of CD.
- The ratio between C1TP (cross-linked peptide) and MMP-1 (protease): Index of the degree of CCL.
- miR-19b: Index of the degree of CCL.

Clinical Indications

HF patients

Competitive Advantage

Allows the identification of alterations of the myocardial collagen network beyond what is given by conventional imaging technology.
The panel is cheaper and less time- and personnel-consuming than available non-invasive imaging methodologies.
The identification of the predominant alteration may influence therapy election.

Proof of Concept

Research in human patients. The proposed biomarkers reflect the myocardial alteration under study. They have a prognostic value for predicting hospitalization for HF or death.

