Co-IVD Development and Licensing
TSP2-based Non-Invasive Liver Fibrosis Diagnostics

Benefits

- Non-invasive serum biomarker approach for staging and monitoring identifying advanced liver fibrosis and at-risk MASH.
- Strong translational rationale: TSP2-based algorithms reflects fibrosis stage and active fibrogenesis, outperforming comparator biomarkers in a large multicentre cohorts.
- Ready for co-development as ELISA/LDT/automated IVD and for companion-diagnostic positioning in MASH and liver fibrosis drug development.

Technology Stage

- Analytical basis established with in-house established/ validated sandwich ELISAs for TSP2, IGFBP7, CD163 and GDF15.
- Solid clinical evidence in large studies of patients with MASH, PSC, PBC, hepatitis B/C, and post-transplant liver fibrosis progression.

Patents

- WO2025099196A1 Biomarker methods and kits for diagnosis, prognosis and/or stratification of liver fibrosis / MASH-related disease states.

Partnership Opportunities

- Co-development of RUO, LDT or CE-IVD/IVDR pathway
- Technology as a service
- Access to well-defined cohorts/studies of patients with fibrotic liver diseases
- License with assay transfer and clinical validation support

Summary

Researchers at University Medical Center Mainz and collaborators have developed a serum biomarker platform measuring matricellular proteins to determine the stage (degree) of liver fibrosis and the speed of fibrosis progression. This platform is based on thrombospondin-2 (TSP2) and clinical chemistry markers for non-invasive fibrosis staging.

In a multicenter European MASLD cohort of 469 biopsy-characterized patients, TSP2 achieved an AUROC of 0.812 for advanced fibrosis and for at-risk MASH, outperforming common comparators such as VCTE, FIB-4, and other more refined combinations. Adding AST, age, platelets, albumin and GGT increased AUROCs to 0.846 for advanced fibrosis and 0.845 for at-risk MASH, which surpasses current markers or combinations. Notably, studies of large cohorts of patients with other fibrotic liver diseases like PSC, PBC, autoimmune hepatitis, or viral hepatitis B or C, with follow-ups up to 5 years, confirm the high predictive value of the TSP2-based algorithms in case finding and for patient monitoring. This strongly supports a scalable co-IVD concept that can be implemented as 2-6 marker assay/algorithm solution in case finding, clinical drug development and patient monitoring.

Technical Approach

From serum or plasma, the method quantifies TSP2 and additional protein markers (IGFBP7, GDF15, TSP4), CD163 and/or clinical chemistry variables using validated immunoassays and algorithm-based interpretation. The analytical foundation includes rigorously validated sandwich ELISAs for TSP2 and the other matricellular markers with reported intra- and inter-assay variation below 10% and 15%, resp. This supports transfer into a co-developed diagnostic workflow. Clinical proof points extend to all fibrotic liver diseases, using biopsy assessments and hard endpoints in long-term follow-up: thus, in post-liver transplant fibrosis progression, TSP2-containing combinations reached AUROCs up to 0.90; and in PSC, the deduced SPARC-PSC composite score reached an AUROC of 0.901.

Market Need

MASH and fibrotic liver diseases in general require highly predictive and easy to perform blood tests to identify patients with significant fibrosis in need of therapies to prevent progression to cirrhosis and primary liver cancer. The studied direct and dynamic markers permit effective patient selection, trial enrolment and treatment monitoring, allowing short and slim antifibrotic efficacy trials and rapid market entry of such therapeutics.

Applications of this technology

- Patient stratification for liver fibrosis trials and treatment monitoring
- Patented companion/complimentary diagnostic development with pharma partners
- Monitoring of fibrosis dynamics and treatment response
- Expansion into all field of fibrotic liver disease including MASH, PSC, PBC, post-transplant, autoimmune and viral hepatitis indications

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