PRESS RELEASE

HepQuant Achieves ISO 13485 Certification to Support Scaling of HepQuant DuO™ to Global Clinical Trials

Internationally recognized certification emphasizes HepQuant's commitment to maintenance of the highest quality management and regulatory compliance standards.

Denver, CO – June 2, 2025 – HepQuant, LLC, a leader in developing noninvasive, blood-based, quantitative testing to assess liver health, is proud to announce ISO 13485 certification as its latest milestone in operational excellence. This internationally recognized certification is a significant achievement that underscores the company's commitment to the highest standards in quality management and regulatory compliance. This milestone enhances HepQuant's abilities to engage in larger, more impactful clinical studies to drive transformative advancements to improve liver health.

The HepQuant DuO™ test is a noninvasive, quantitative test that measures blood flow to the liver to assess disease severity, progression, and improvement. Numerous studies by pharmaceutical companies and academic research institutions have used HepQuant DuO testing for evaluation of serum samples collected in clinical trials aimed at assessing liver function, physiology, and impairment across the spectrum of clinical trials focused on liver disease. ISO 13485 certification validates HepQuant's robust processes and stringent quality controls, ensuring that products and services not only meet but also exceed industry benchmarks.

Dr. Gregory T. Everson, CEO and founder commented, "Clinical trials of advanced liver disease are often weighted with invasive procedures such as biopsies, endoscopies, and hepatic pressure measurements. HepQuant DuO delivers noninvasive, direct, reproducible measurements of liver function and physiology."

The test generates a Disease Severity Index (DSI), based on the measurement of cholate uptake by the liver, to quantify liver function and portal systemic shunting. Sample collection for HepQuant DuO testing requires the ingestion of cholate, followed by two blood draws at 20 and 60 minutes. The scope of HepQuant's ISO 13485 certification is the design, development, and manufacture of cholate tests and software used for cholate analysis. Elevated certification allows HepQuant to broaden testing for drug development at clinical sites in the EU/EEA and downstream. The certification enables global expansion of HepQuant testing to support clinical studies focused on various presentations of liver disease, including MAFLD/MASH fibrosis and cirrhosis, viral hepatitis, biliary disease, alcohol associated liver disease, and end-stage liver disease.

About HepQuant

HepQuant has developed noninvasive, blood-based, quantitative tests that assess liver health by measuring critical liver cell processes and blood flow to the liver. Our test results, in conjunction with other clinical assessments, inform healthcare providers' clinical decisions to achieve more effective management of patients with advanced liver disease. Knowing where a patient falls on the disease spectrum informs personalized treatment decisions for that individual. HepQuant is a privately held diagnostics company based in Denver, Colorado. Learn more at HepQuant.com.

HepQuant DuO is a Laboratory Developed Test (LDT). This test was developed and its performance characteristics determined by HepQuant, LLC in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration

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