PRESS RELEASE

FDA Approves the HepQuant SHUNT® Liver Diagnostic Test to Quantify Risk of Large Esophageal Varices in Adult Patients with Compensated Cirrhosis (Child Pugh Class A)

DENVER, Colo., June 23, 2026 —HepQuant announced that the U.S. Food and Drug Administration (FDA) has granted the premarket approval (PMA) for the HepQuant SHUNT® Liver Diagnostic Test. The test generates a Disease Severity Index (DSI) score which aids in identifying patients unlikely to require esophagogastroduodenoscopy (EGD) at the time of testing. A DSI score below the clinically validated threshold of 18.3 can be used in patients with compensated cirrhosis (Child Pugh Class A), age 22 years or older, undergoing screening or surveillance for esophageal varices to identify those patients unlikely to have large esophageal varices.

Chronic liver disease is inflicting massive clinical and economic burden on global healthcare systems, with over 52 thousand deaths in the US alone each year.[1,2] The worldwide prevalence of compensated cirrhosis, from all etiologies, was 112 million in 2017.[1] Better tools are needed to improve patient management as patients often do not seek care until symptoms appear after the disease has already progressed.[3,4] HepQuant's mission is to improve the lives of people with, or at risk for, liver diseases by delivering quantitative, accurate measurements of liver health across the full spectrum of disease severity to clinicians, researchers, drug developers and patients.

"HepQuant is proud to reach this milestone for our company to enhance clinical management for the patients and clinicians we serve," commented Gregory T. Everson, M.D. and Chief Executive Officer of HepQuant, *"This approval validates years of scientific innovation, clinical research, and collaboration with leading medical centers, culminating in a technology that has met the FDA's most rigorous safety and effectiveness standard for medical devices. The FDA PMA approval pathway demands extensive evidence demonstrating that a diagnostic not only performs accurately and consistently but also provides clinically actionable information."*

About the Test

The HepQuant SHUNT® Liver Diagnostic Test assesses the pathophysiologic processes common to chronic liver disease with Child Pugh A (CPA) cirrhosis. The clearances of intravenously (IV)-administered-cholate and orally-administered-cholate are liver specific functions that are determined by systemic and portal blood inflows to the liver, respectively, as well as on the specific hepatocyte function of cholate uptake. Increasing impairment of these cholate clearances correlates with increasing severity of liver disease and risk for adverse clinical outcomes.

About the Pivotal Clinical Validation Study

Clinical performance of the HepQuant SHUNT® Liver Diagnostic Test was evaluated in the SHUNT-V Study for Varices (ClinicalTrials.gov NCT03583996). The SHUNT-V study was a prospective, U.S., multicenter, single-arm diagnostic clinical study in adults with chronic liver disease who were scheduled for EGD. The purpose of the study was to validate the prespecified Disease Severity Index (DSI) cutoff of ≤18.3 for identifying subjects with chronic liver disease who would be unlikely to have large esophageal varices at EGD. In the SHUNT-V study, validation criteria for negative likelihood ratio and sensitivity were met and the diagnostic performance of DSI 18.3 for "rule out" large esophageal varices was excellent with sensitivity 100% and negative predictive value 100% (Table 1). The clinical validation dataset included 195 subjects with evaluable HepQuant SHUNT® Liver Diagnostic Tests. As referenced in Table 2, the cohort age range was 23-85 (mean age

62 years) and 49% were male, 87% were overweight, 64% were obese, 52% had diabetes, and 48% had Metabolic Dysfunction-Associated Steatohepatitis (MASH).

Table 1: Clinically Validated Performance[a]	**Value**	**95% CI**
Sensitivity	100.00%	85.18% to 100.00%
Specificity	31.98%	25.08% to 39.51%
Positive Predictive Value	16.43%	10.71% to 23.62%
Negative Predictive Value	100.00%	93.51% to 100.00%

a Confidence intervals for sensitivity, specificity, positive predictive value, and negative predictive value are "exact" Clopper-Pearson confidence intervals.
b Subjects may have had more than one liver disease etiology; therefore, etiology percentages do not sum to 100%

Table 2: Characteristics and Demographics			
	Overall (n=195)	**Large Esophageal Varices Absent (n=172)**	**Large Esophageal Varices Present (n=23)**
Age, years	61.5 ± 10.4	61.6 ± 10.7	61.1 ± 8.4
Sex, male	95 (48.7%)	83 (48.3%)	12 (52.2%)
BMI, kg/m2	33.1 ± 7.1	33.2 ± 7.1	32.2 ± 6.6
BMI >25 kg/m2	169 (86.7%)	151 (87.8%)	18 (78.3%)
BMI >30 kg/m2	124 (63.6%)	108 (62.8%)	16 (69.6%)
Diabetes	102 (52.3%)	91 (52.9%)	11 (47.8%)
Liver disease etiology[b]			
Metabolic dysfunction-associated steatohepatitis	93 (47.7%)	83 (48.3%)	10 (43.5%)
Hepatitis C	48 (24.6%)	43 (25.0%)	5 (21.7%)
Alcoholic liver disease	31 (15.9%)	26 (15.1%)	5 (21.7%)
Cryptogenic cirrhosis	15 (7.7%)	11 (6.4%)	4 (17.4%)
Autoimmune hepatitis	14 (7.2%)	14 (8.1%)	0 (0.0%)
Hepatitis B	3 (1.5%)	3 (1.7%)	0 (0.0%)
Hereditary hemochromatosis	2 (1.0%)	2 (1.2%)	0 (0.0%)
Primary biliary cholangitis	2 (1.0%)	2 (1.2%)	0 (0.0%)

1. Devarbhavi H, et. al., Global burden of liver disease: 2023 update, Journal of Hepatology, 2023; doi: 10.1016/j.jhep.2023.03.017.
2.http://wonder.cdc.gov/controller/saved/D158/D470F661 . 3. D'Amico G, Garcia-Tsao G, Pagliaro L. *Natural history and prognostic indicators of survival in cirrhosis: a systematic review of 118 studies.* J Hepatol. 2006;44(1):217-231. 4. Burton J, et al., *Gastro Hep Adv,* 2025. doi:10.1016/j.gastha.2025.100814

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. HepQuant's mission and vision are driven by our commitment to transform the management of liver disease. 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. Sample analysis is limited to use only in the CAP accredited, CLIA certified HepQuant Analytical Testing Laboratory. HepQuant is a privately held diagnostics company based in Denver, Colorado. Learn more at HepQuant.com.

Contact

Joellyn Enos, Chief Commercial Officer
Joellyn.Enos@HepQuant.com
303.268.7069