Touch-Activated Phlebotomy (TAP) and the HepQuant DuO Test: Field-Deployable Liver Function Assessment for Military Settings

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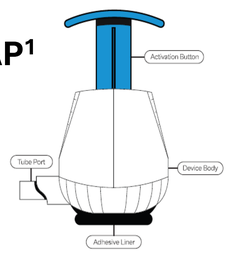
Background & Aims

- The HepQuant SHUNT® Liver Diagnostic test was FDA approved (June 18, 2026).
- The **HepQuant DuO®** test is a simplified version of the SHUNT test that measures global liver function not quantified by standard liver chemistries.
- Potential operational applications include screening for subclinical liver dysfunction, monitoring hepatic reserve during hepatotoxic exposures, assessing recovery after trauma or surgery.
- Venipuncture (VP) limits deployment in resource-constrained settings.
- We evaluated analytical and clinical equivalence of the minimally invasive, field-deployable **Touch Activated Phlebotomy (TAP®)** device versus venipuncture for DuO blood collection.

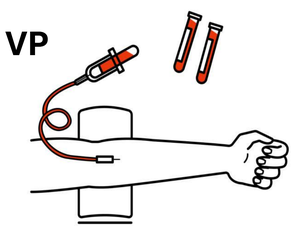
Methods

- Controlled crossover study of 10 subjects comparing Disease Severity Index (DSI), pain, and ease of collection of TAP versus VP
- VP blood samples stored in gel microtainers at ambient temperature analyzed after 0, 1, 3, 7 days

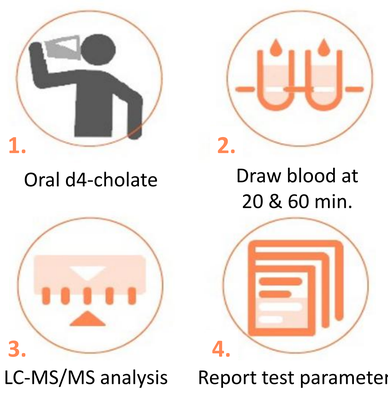
TAP[1]



VP



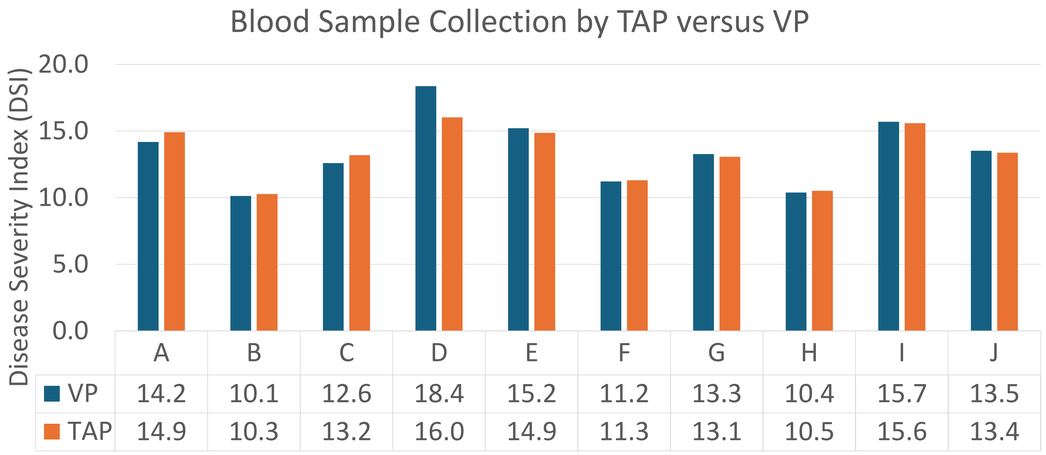
HepQuant DuO Test[2-4]:



Results

TAP vs VP

- DSI values demonstrated no clinically meaningful differences between TAP and VP, with paired differences remaining within the predefined clinical equivalency range of ±2 units.



	A	B	C	D	E	F	G	H	I	J
VP	14.2	10.1	12.6	18.4	15.2	11.2	13.3	10.4	15.7	13.5
TAP	14.9	10.3	13.2	16.0	14.9	11.3	13.1	10.5	15.6	13.4

*Disease Severity Index (DSI) is a measure of overall liver health from 0 (healthy) to 50 (end-stage liver disease)

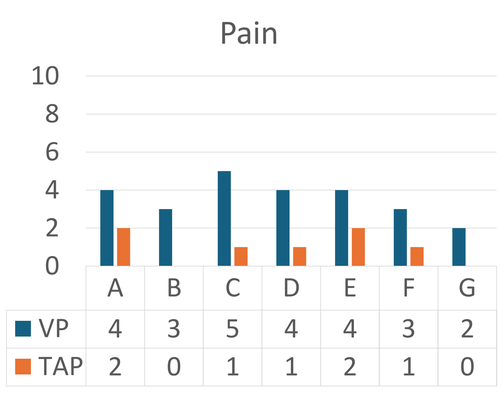
Stability

- d4-cholate concentrations remained stable for 7 days under ambient storage conditions in both whole blood and serum.
- DSI values remained within ±2 units throughout the storage period, with coefficients of variation ≤ 3.2%.

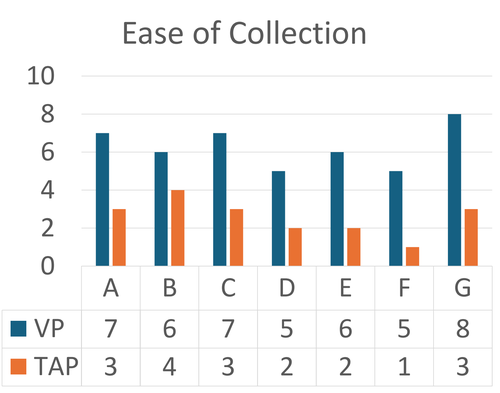
% Difference Between Baseline (Day 0) and Day 7			
	20-min [d4-CA]	**60-min [d4-CA]**	**DSI**
Whole Blood	2.0%	8.0%	3.2%
Serum	1.0%	8.8%	1.7%

Tolerability Survey

- Blood collection by TAP was less painful and easier to collect



	A	B	C	D	E	F	G
VP	4	3	5	4	4	3	2
TAP	2	0	1	1	2	1	0



	A	B	C	D	E	F	G
VP	7	6	7	5	6	5	8
TAP	3	4	3	2	2	1	3

Conclusion

- The TAP device enables reliable, minimally trained, field-ready capillary blood collection for the HepQuant DuO test.
- Combined with demonstrated ambient-temperature stability and ability to ship samples back to centralized laboratories for LC-MS/MS analysis, this system supports operational deployment of advanced liver function testing.
- These findings highlight the potential for TAP-enabled DuO testing to enhance diagnostic capability in deployed military environments, prolonged field care settings, and low-infrastructure locations.

References

[1] YourBio Health, TAP® Micro Select IFU.
[2] McRae et al., *Clin Transl Sci,* 2024.
[3] McRae et al., *Basic Clin Pharmacol Toxicol,* 2024.
[4] Helmke et al., *J Appl Lab Med,* 2024.

Disclosures

JP, KH, KN, JR, JI, TS, KW, and GTE are employees of HepQuant, LLC. JI and GTE are equity members of HepQuant, LLC. MPM is a paid contractor for HepQuant, LLC. MPM and GTE have patents pending.

HepQuant DuO is a Laboratory Developed Test (LDT) and is not FDA approved. Test results should be used together with other clinical or laboratory information or results to inform the provider's decisions regarding procedures, treatments, or interventions.

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