

# **Diagnosing NASH and Assessing NASH Disease Severity with HepQuant-STAT, a Simple Quantitative Liver Function Test**

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**HepQuant-STAT is for investigational use only  
and is not approved by the FDA**

# Background

- **It is difficult to diagnose NASH and assess disease severity.**
- **Biopsy is invasive and can exhibit 40% variability in staging (Ratziu, et al, 2005).**
- **The goal of this pilot study was to determine if a simple quantitative test of global liver function, the HepQuant-STAT test, could diagnose NASH and assess NASH disease severity.**

# Healthy Controls and NASH Patients

## 50 Healthy Controls

### BMI status

- 30 Normal Weight (BMI 18.5 – 25)
- 16 Overweight (BMI 25 – 30)
- 4 Obese (BMI > 30)

## 31 NASH Patients

### Biopsy Diagnosis

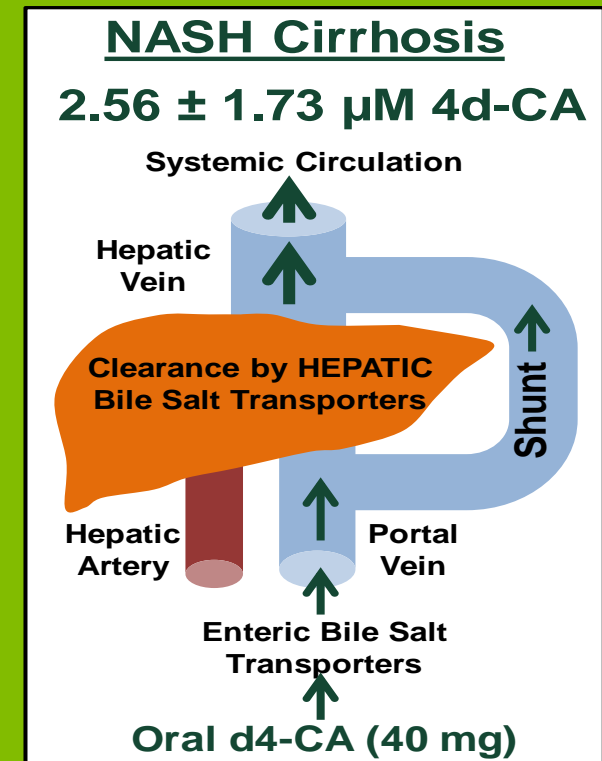
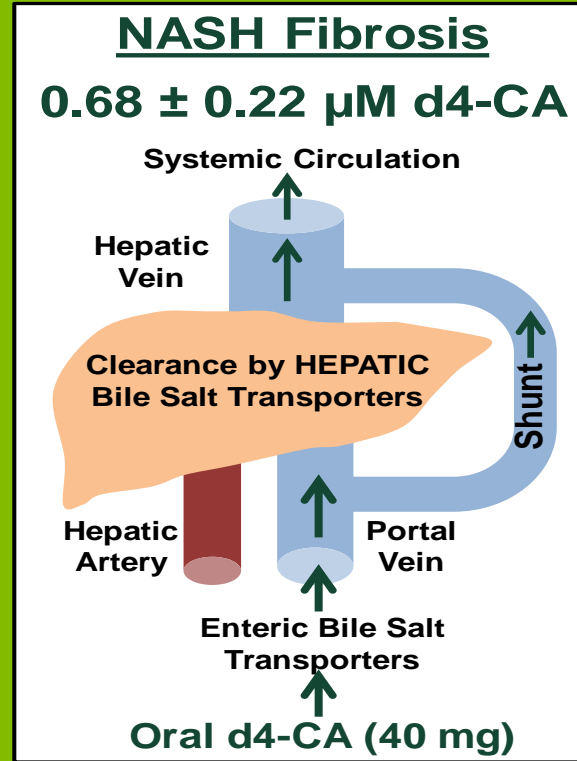
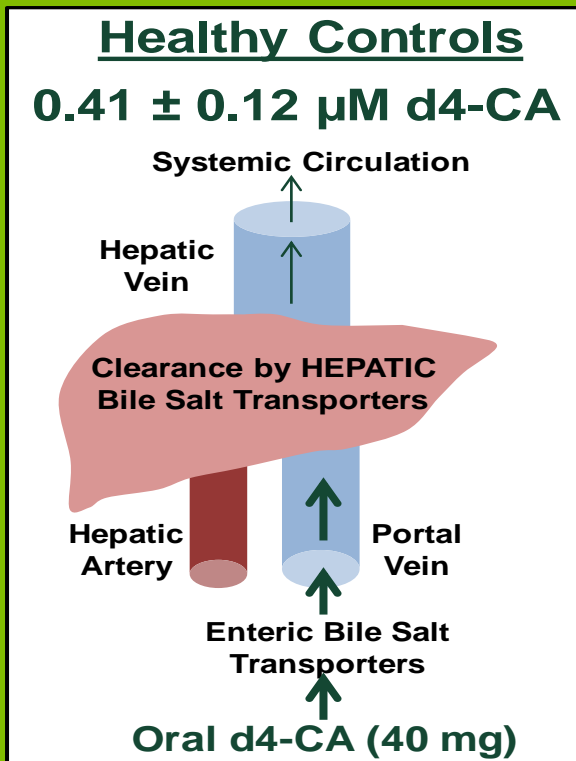
- 27 Biopsy-diagnosed NASH
- 4 Cryptogenic cirrhosis w obesity (presumed late-stage NASH)

### Biopsy Stage and Clinical Status

- 4 Brunt-Kleiner F1
- 4 Brunt-Kleiner F2
- 5 Brunt-Kleiner F3
- 18 Brunt-Kleiner F4 (cirrhosis)
  - 9 compensated cirrhosis
  - 9 decompensated cirrhosis

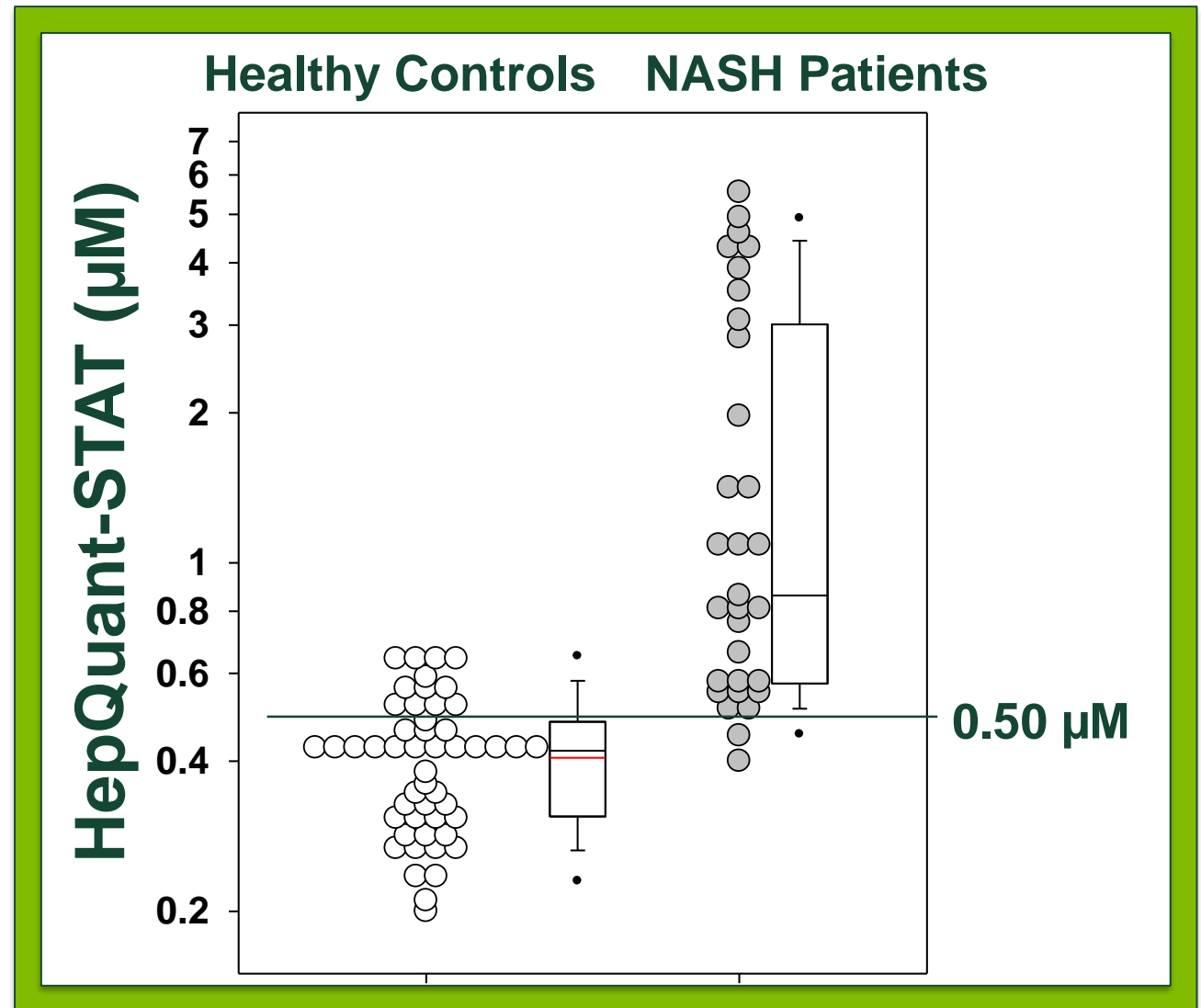
# HepQuant-STAT: a Simple Liver Function Test

1. Patient drinks 40 mg deuterated cholic acid (d4-CA) in juice at time 0.
2. A single peripheral blood sample at time 60 min is analyzed for d4-CA.



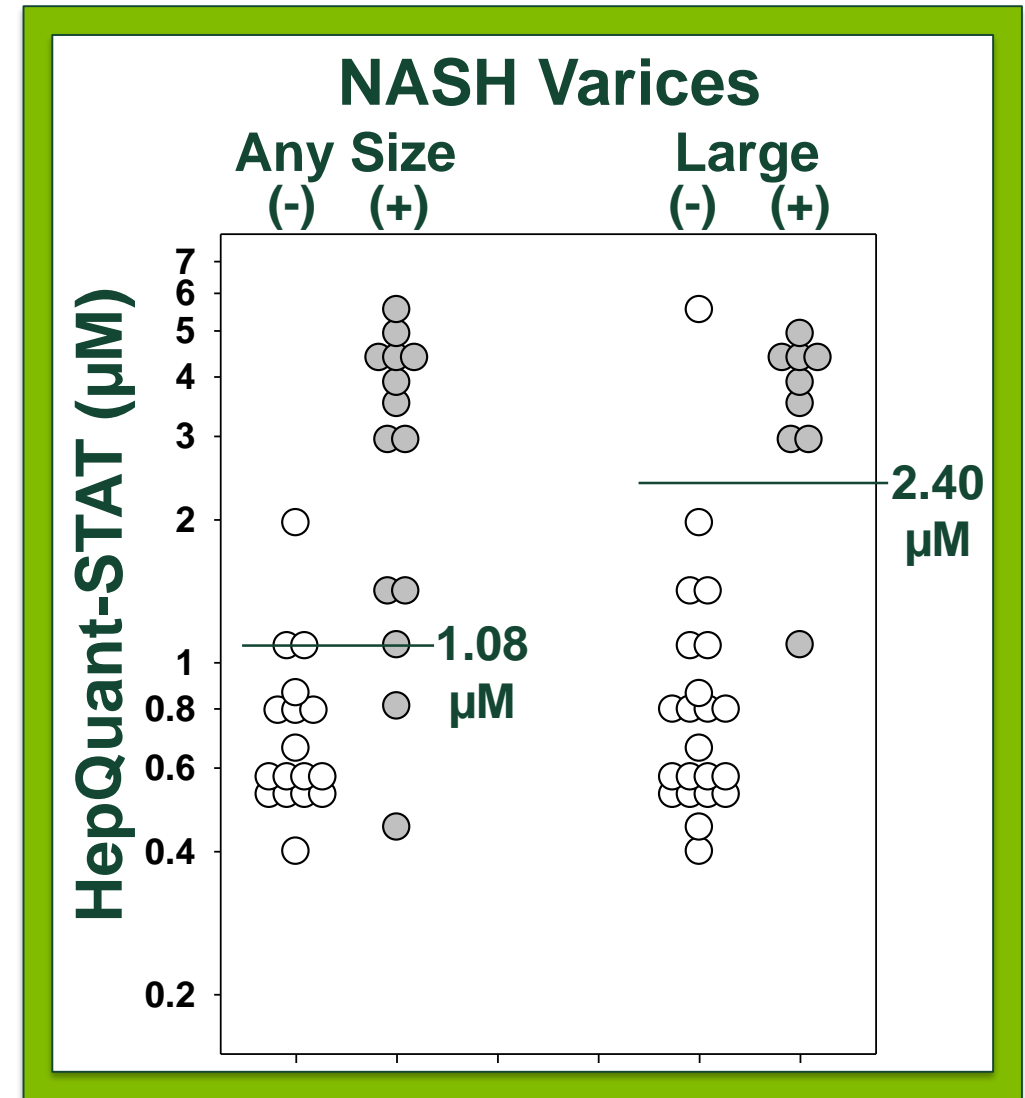
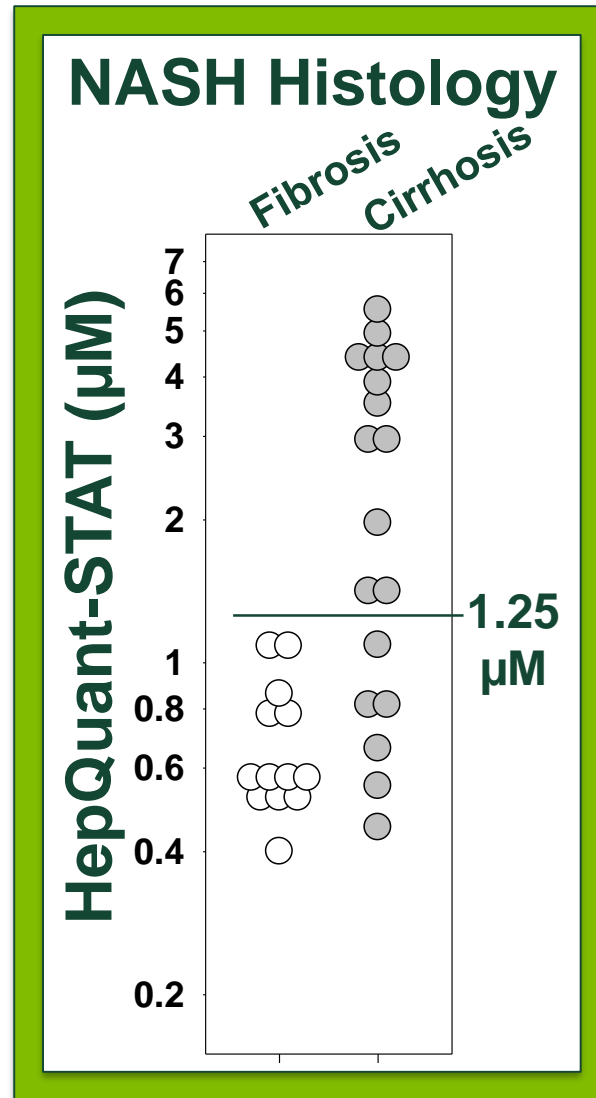
## HepQuant-STAT could differentiate NASH Patients from Healthy Controls

A cutoff of  $> 0.50 \mu\text{M}$  could identify NASH Patients with excellent Sensitivity (94%) and Negative Predictive Value (NPV) (95%).



HepQuant-STAT could differentiate cirrhotic (F4) NASH Patients (n=18) from those with (F1-3) Fibrosis.

HepQuant-STAT could differentiate those NASH Patients with any size varices (n=14) and those with large varices (n=9).



# Increasing HepQuant-STAT Test Values were associated with Increasingly Severe Disease Manifestations

	<b>AUROC c-statistic</b>	<b>Optimum Cutoff</b>	<b>Sens.</b>	<b>Spec.</b>	<b>PPV</b>	<b>NPV</b>	<b>Youden Index (J)</b>
<b>Diagnosing NASH</b>	<b>0.93</b>	<b>STAT &gt; 0.50 <math>\mu</math>M</b>	<b>94%</b>	<b>76%</b>	<b>71%</b>	<b>95%</b>	<b>0.70</b>
<b>Diagnosing NASH Var</b>	<b>0.90</b>	<b>STAT &gt; 1.08 <math>\mu</math>M</b>	<b>86%</b>	<b>88%</b>	<b>86%</b>	<b>88%</b>	<b>0.74</b>
<b>Diagnosing NASH Cirrhosis</b>	<b>0.86</b>	<b>STAT &gt; 1.25 <math>\mu</math>M</b>	<b>67%</b>	<b>100%</b>	<b>100%</b>	<b>68%</b>	<b>0.67</b>
<b>Diagnosing NASH Lg Var</b>	<b>0.93</b>	<b>STAT &gt; 2.40 <math>\mu</math>M</b>	<b>89%</b>	<b>95%</b>	<b>89%</b>	<b>95%</b>	<b>0.84</b>



# Conclusions

- **HepQuant-STAT, a simple quantitative liver function test, could be a minimally-invasive alternative to biopsy for the diagnosis of NASH.**
- **HepQuant-STAT could assess NASH disease severity by identifying patients at risk of varices, cirrhosis, and large varices.**

**Thank you very much for  
your attention!**

**Questions?**