

# A POINT-OF-CARE SOLUTION FOR LIVER FUNCTION TESTING IN DEVELOPING COUNTRIES

PATRICK BEATTIE – AACC OAK RIDGE CONFERENCE 2010



## DIAGNOSTICS FOR ALL



# Why liver function?

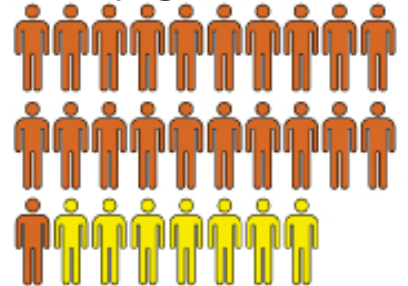
- Drug-induced liver damage
  - ARVs and ATTs
- Hepatitis
- Chronic disease

## Liver Damage Caused by HIV/AIDS Medications

United States:



Developing countries:



 = suffering liver damage     = 100,000 people

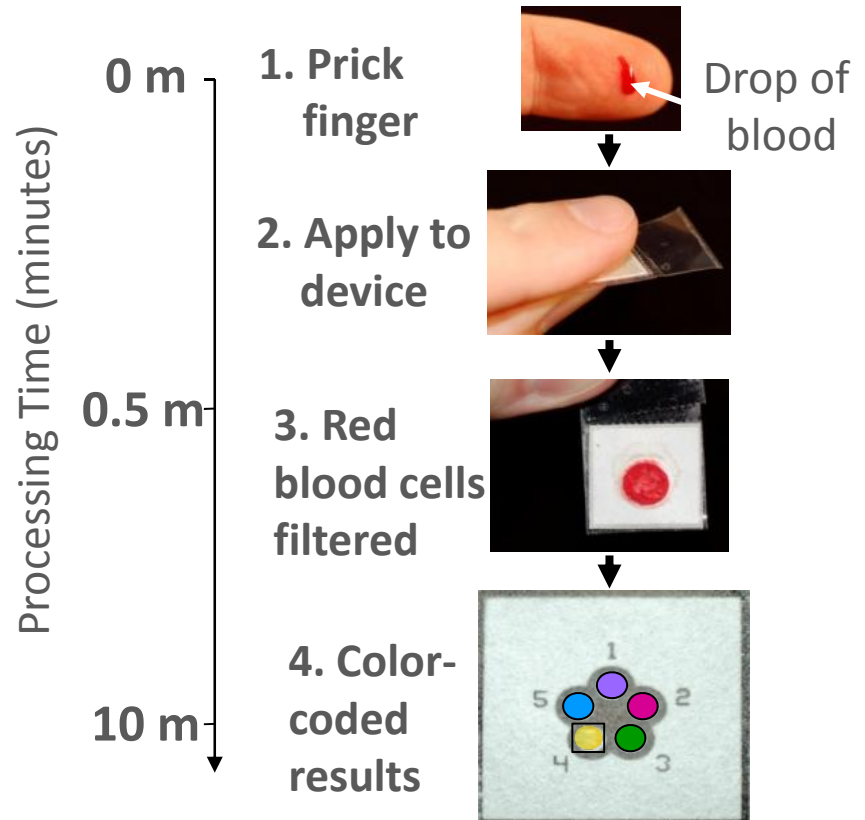


# User needs and concept

## User needs

- Portability
- Semi-quant. “bins”
- Fingertick sample
- Stability

## Concept





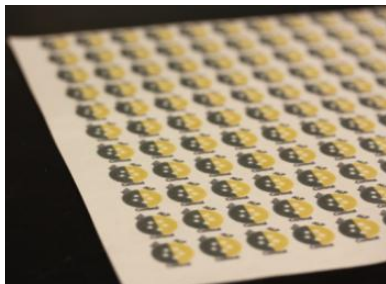
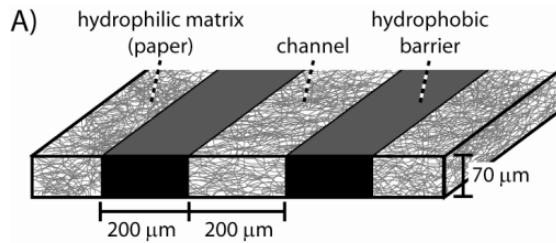
# Patterned paper as a POC platform

- Why paper?

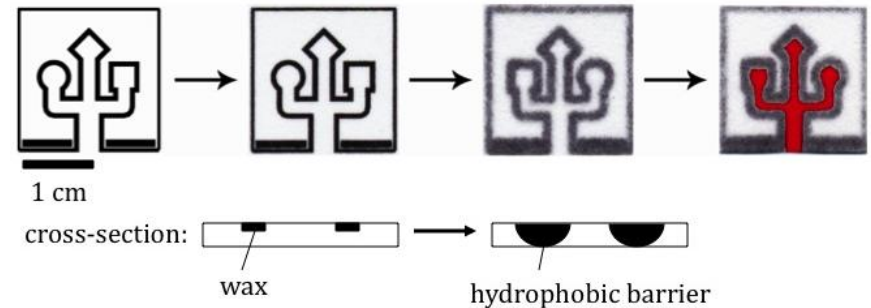
- Low-cost
- Easy to transport
- Disposable
- Wicks fluid
- Covalent binding

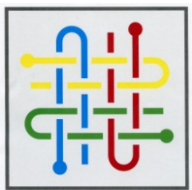
- Wax printing – “zero” cost

- <3 minutes/sheet
  - 0.029 cents/device total cost\*
  - *One printer can make over 71 million devices/year*
- \*Patterning cost based on Xerox



132 devices per sheet





# Specifications and assay selection

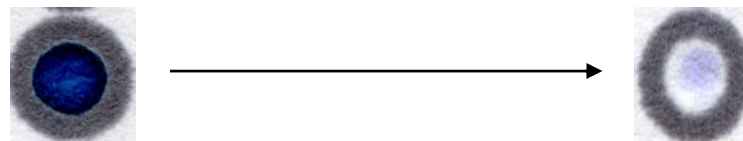
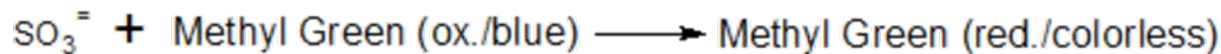
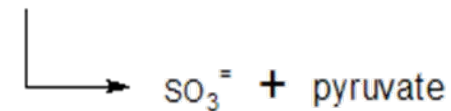
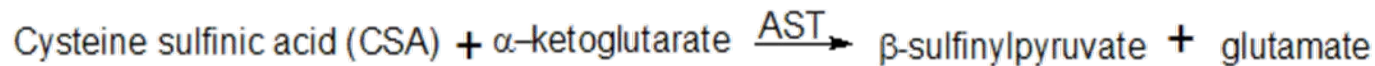
- Specifications:

- ALT and AST

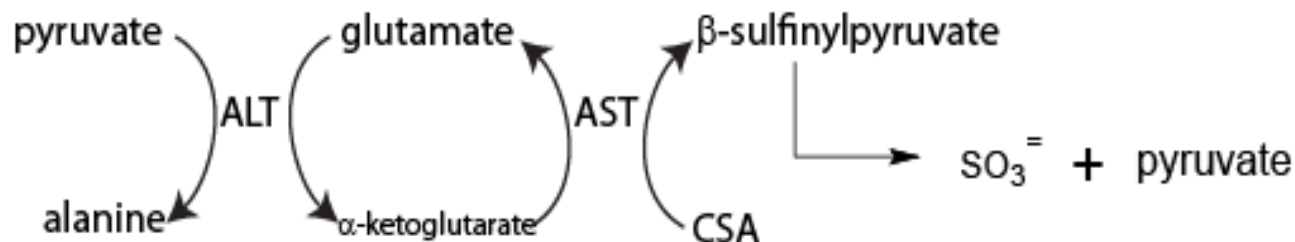
- 1x, 3x, 5x break points

- Visual distinction

- AST:



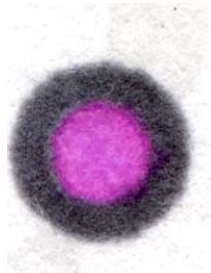
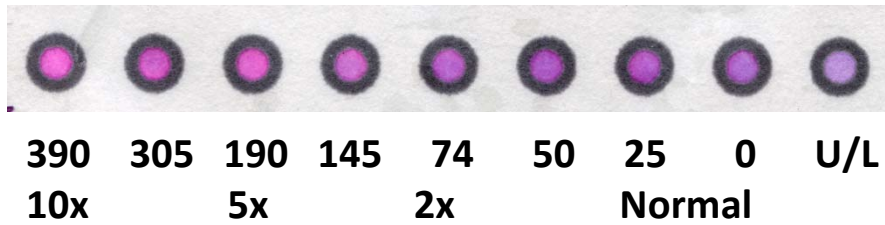
- ALT:



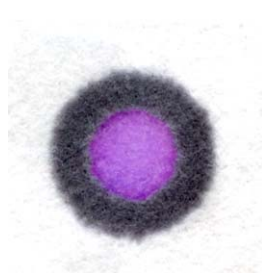


# Results - visual

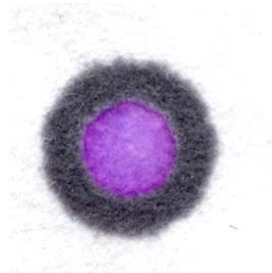
## ALT Assay



190 U/L

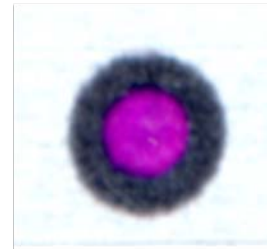
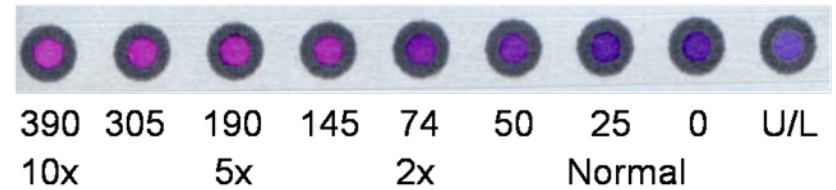


74 U/L

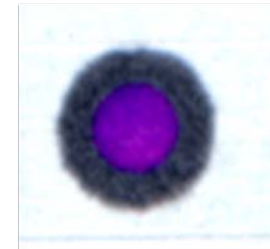


25 U/L

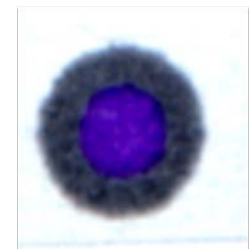
## AST Assay



190 U/L



74 U/L

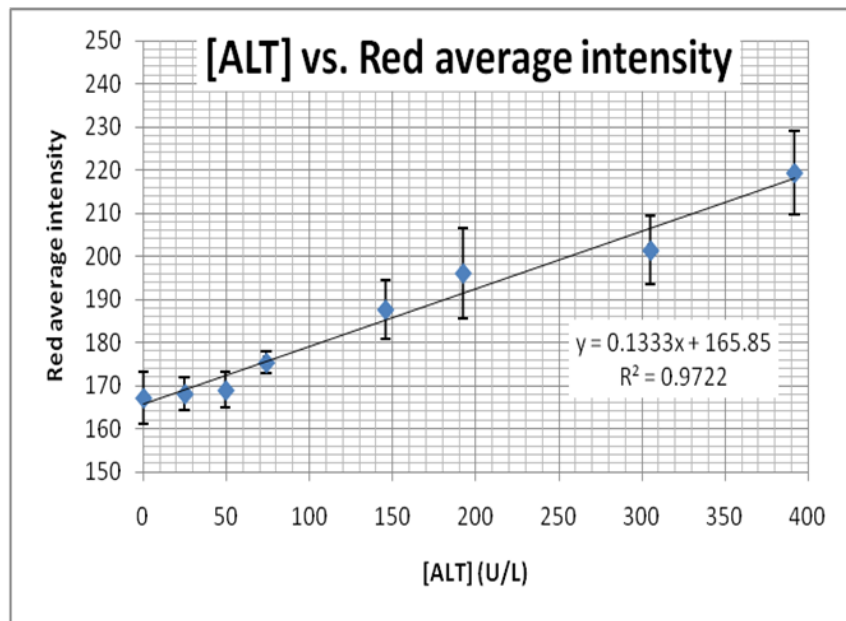


25 U/L

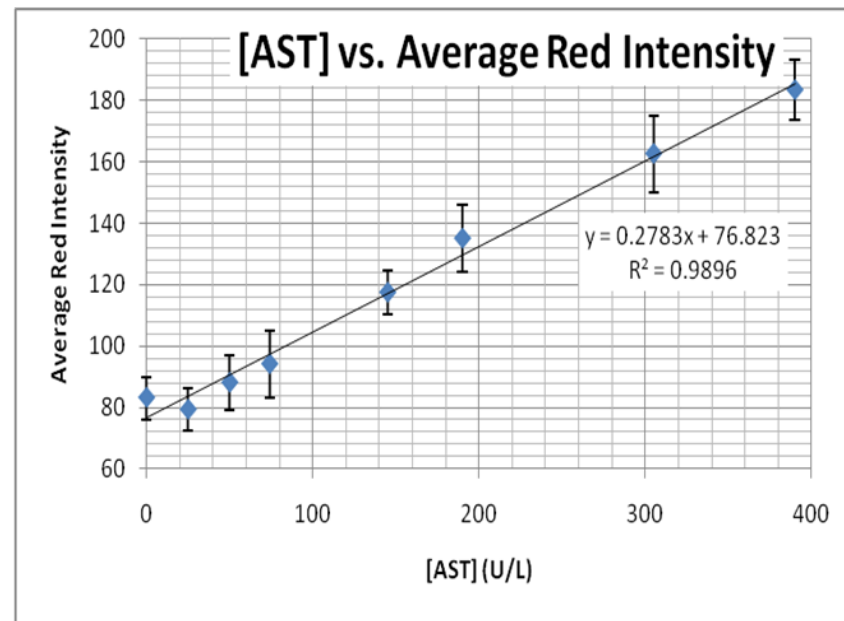


# Results - Quantitative

## ALT Assay



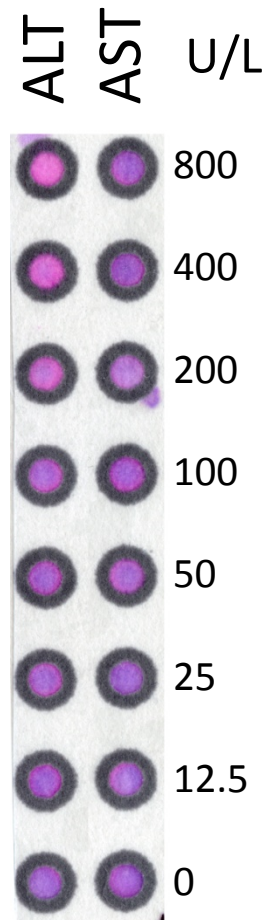
## AST Assay





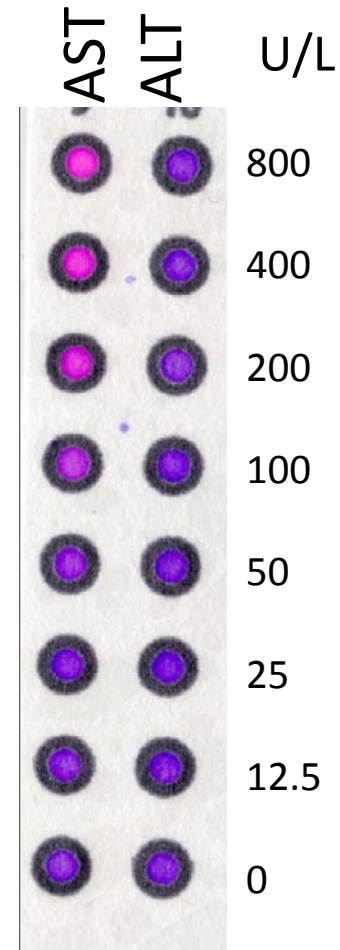
# Results – Cross reactivity

## ALT Assay



No cross-reactivity  
seen, even at high  
concentrations

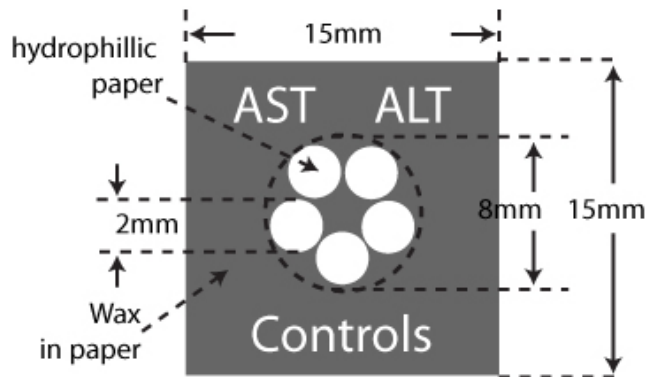
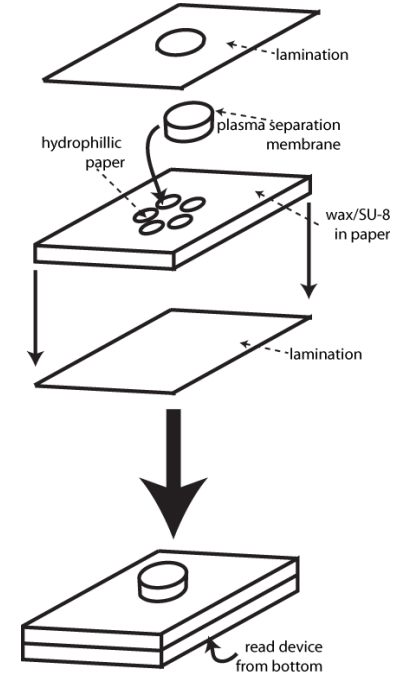
## AST Assay





# Device integration

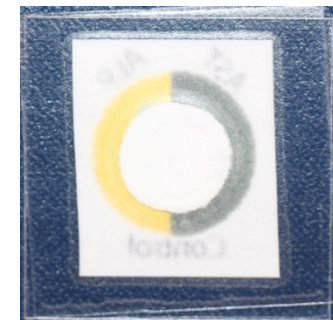
- 5 zones
- Plasma separation membrane
- Lamination



Neg. Ctrl

Pos. Ctrl

Back view





# Conclusions

- Visual distinction at important break points
- Quantitative results using scanner
- No cross reactivity between transaminases
- Further optimization (ALT) and integration are next steps



# Acknowledgements

- The Diagnostics For All team
  - Drs. Kumar, Rolland, Ryan
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- Bill and Melinda Gates Foundation