

## An immunochromatographic test for measurement of Alanine Aminotransferase 1 (ALT1) at Point of Care

---

David Anderson<sup>1,2,3</sup>

Deputy Director (Partnerships), Burnet Institute

[david.anderson@burnet.edu.au](mailto:david.anderson@burnet.edu.au)

**M. Garcia**<sup>1,3</sup>, H. Van<sup>1,3</sup>, F. Li<sup>1,3</sup>, Z. Zhang<sup>2</sup>, J. Zhu<sup>2</sup>, Y. Feng<sup>2</sup>, M. Hellard<sup>3</sup>, J. Doyle<sup>3</sup>, J. Li<sup>4</sup>

<sup>1</sup>Global Health Diagnostics Laboratory, Burnet Institute, Melbourne, Australia,

<sup>2</sup>Nanjing BioPoint Diagnostics, Nanjing, PR China,

<sup>3</sup>Burnet Institute, Melbourne, Australia,

<sup>4</sup>Jiangsu Provincial People's Hospital, Nanjin

11<sup>th</sup> Aust Viral Hep, August 2018



## An immunochromatographic test for measurement of Alanine Aminotransferase 1 (ALT1) at Point of Care

---

Disclosures:

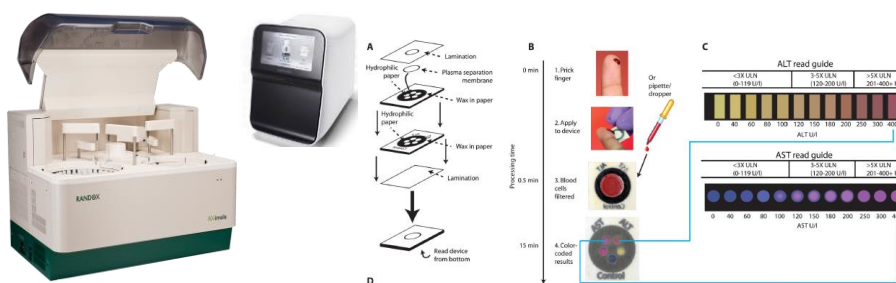
D. Anderson is Founder and CEO of Nanjing BioPoint Diagnostics (Burnet spinoff)

D. Anderson, M. Garcia, H. Van, Z. Zhang are inventors on PCT patent for ALT test



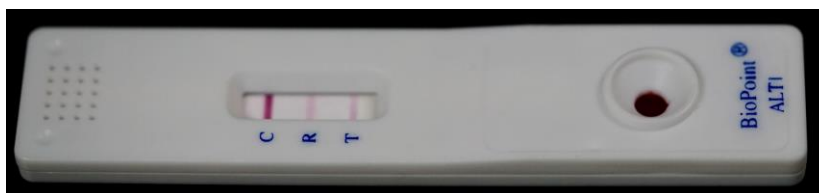
## POC test for ALT – Why?

- ALT (Alanine aminotransferase) is a commonly used marker of liver damage (acute and chronic)
- Recommended in monitoring of chronic HBV (etc)
  - Y. Shimakawa et al J.Hepatol 2018 – “TREAT-B”
- EASL guidelines suggest 40 U/L as upper limit of normal
- ALT enzymatic reaction requires expensive instruments, or colorimetric tests that are not sensitive in the relevant range



## POC test for ALT – How?

- Measure ALT1 as a protein antigen (ALT1 only), rather than enzymatic activity (ALT1 plus ALT2)
- Lateral flow strip with anti-ALT1 antibody test line, colloidal gold anti-ALT1 detection reagent
- 40  $\mu$ l whole blood or 15  $\mu$ l plasma, add buffer, wait 20 min
- Read visually (by comparison with R line of 40 U/L) or with optional instrument reader for quantitation



# Example results for BioPoint® lateral flow ALT1



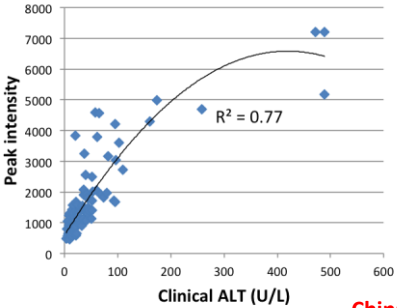
# Correlation with standard (enzymatic) ALT

40 µl whole blood

ALT1 rapid	Clinical ALT		Total
	≥40U/L	<40U/L	
≥40U/L	28	7	35
<40U/L	5	66	71
Total	33	73	106

**Visual read:**

Sensitivity	85 %
Specificity	90 %
Accuracy	89 %



China, n=106

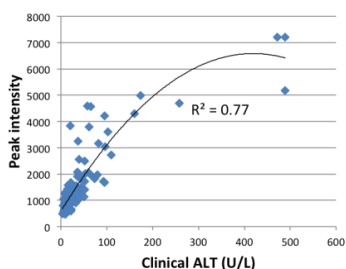
## Correlation with standard (enzymatic) ALT

### 40 µl whole blood

ALT1 rapid	Clinical ALT		Total
	≥40U/L	<40U/L	
≥40U/L	28	7	35
<40U/L	5	66	71
Total	33	73	106

#### Visual read:

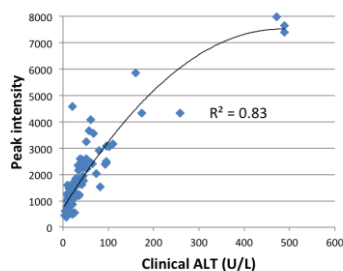
Sensitivity	85 %
Specificity	90 %
Accuracy	89 %



### 15 µl plasma

ALT1 rapid	Clinical ALT		Total
	≥40U/L	<40U/L	
≥40U/L	31	11	42
<40U/L	2	62	64
Total	33	73	106

Sensitivity	94 %
Specificity	85 %
Accuracy	88 %



China, n=106  
(similar results in Melbourne, n= 293 plasma)

## Conclusions

- The BioPoint® ALT1 test is specific for ALT1 only
  - No reactivity with ALT2 (not shown)
- Good correlation and accuracy compared to enzymatic ALT
- Suitable for use with whole blood or plasma
  - Plasma samples are stable for very long periods at ambient temp
- Visual (semi-quantitative) or instrument (quantitative)
- The BioPoint® ALT1 test should facilitate improved liver disease monitoring in remote and resource-poor settings
- May be especially valuable for monitoring of chronic HBV in combination with HBeAg (Y. Shimakawa et al, 2018)

## Thankyou

---

Video of test available – see me afterwards

david.anderson@burnet.edu.au

