

Burnet Institute and capacity in development (and deployment) of POC tests

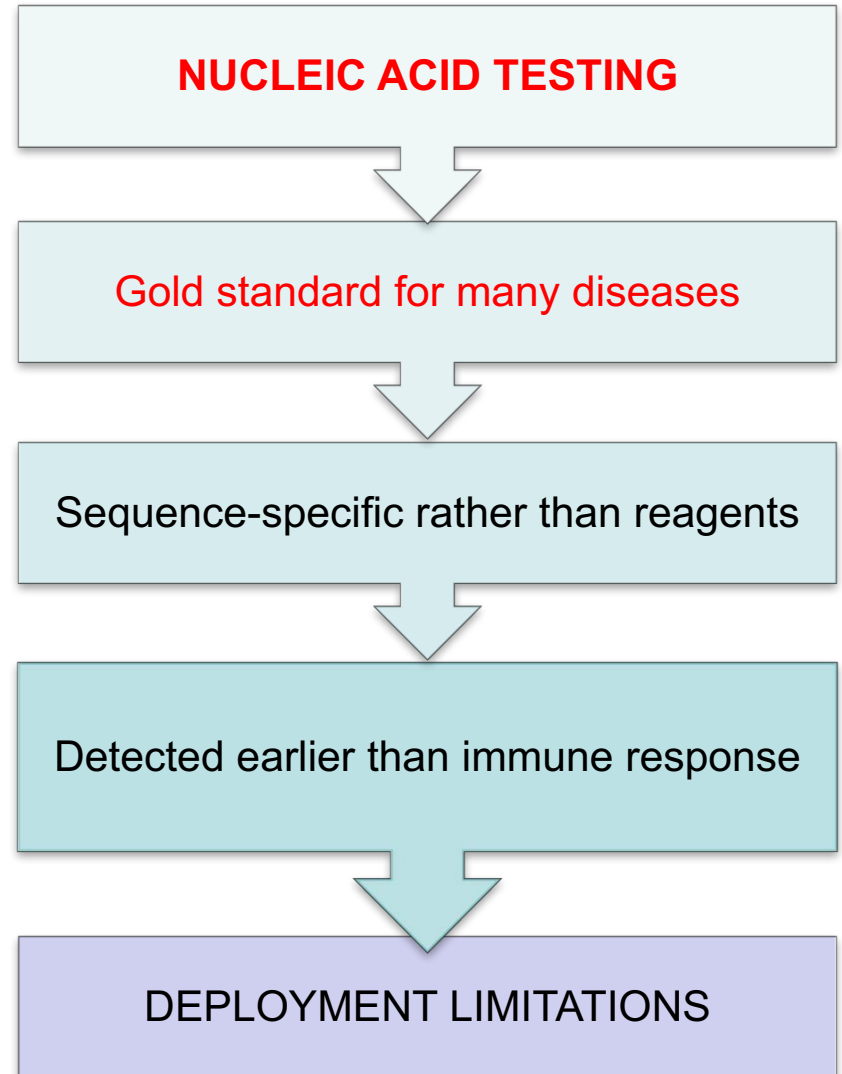


A/Prof David Anderson

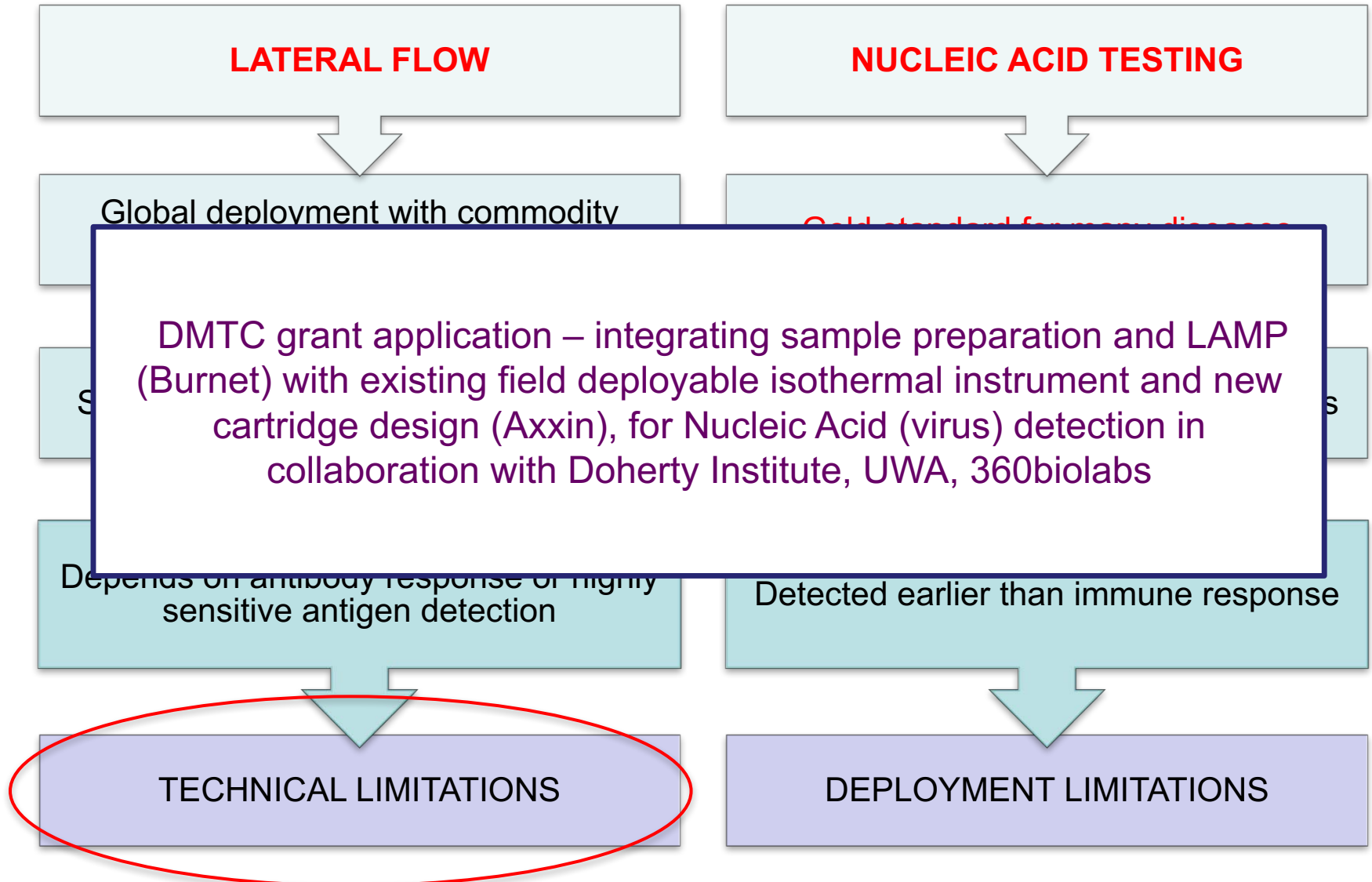
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APPRISE annual meeting, August 2017

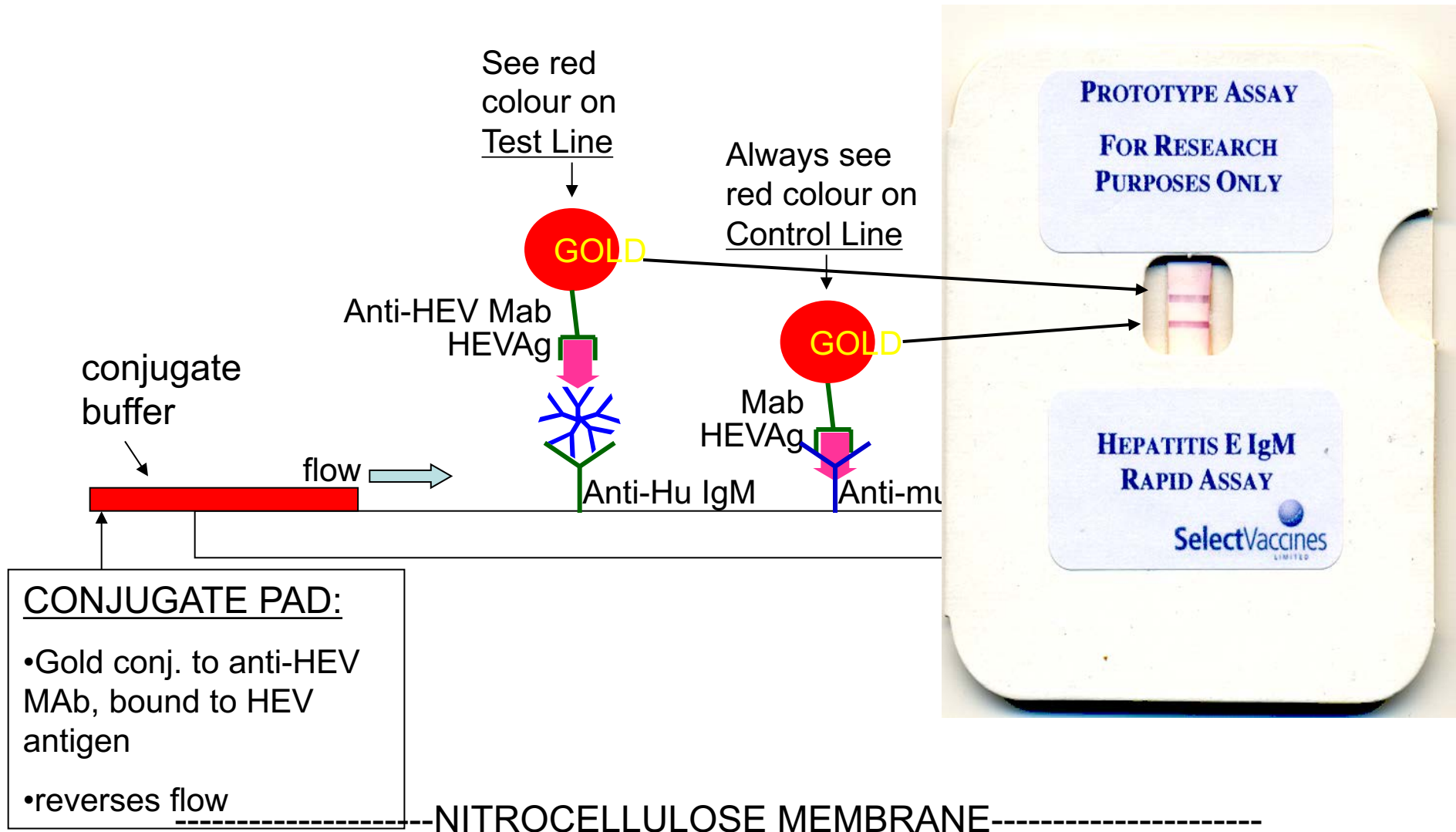
POC testing and lateral flow chromatography



POC testing and lateral flow chromatography



HEV IgM Rapid Test: Reverse Flow Technology



Priority Diagnostics Roadmap

UNMET MEDICAL NEEDS

- Access to treatment, control of disease spread, targeting of vaccines or drugs

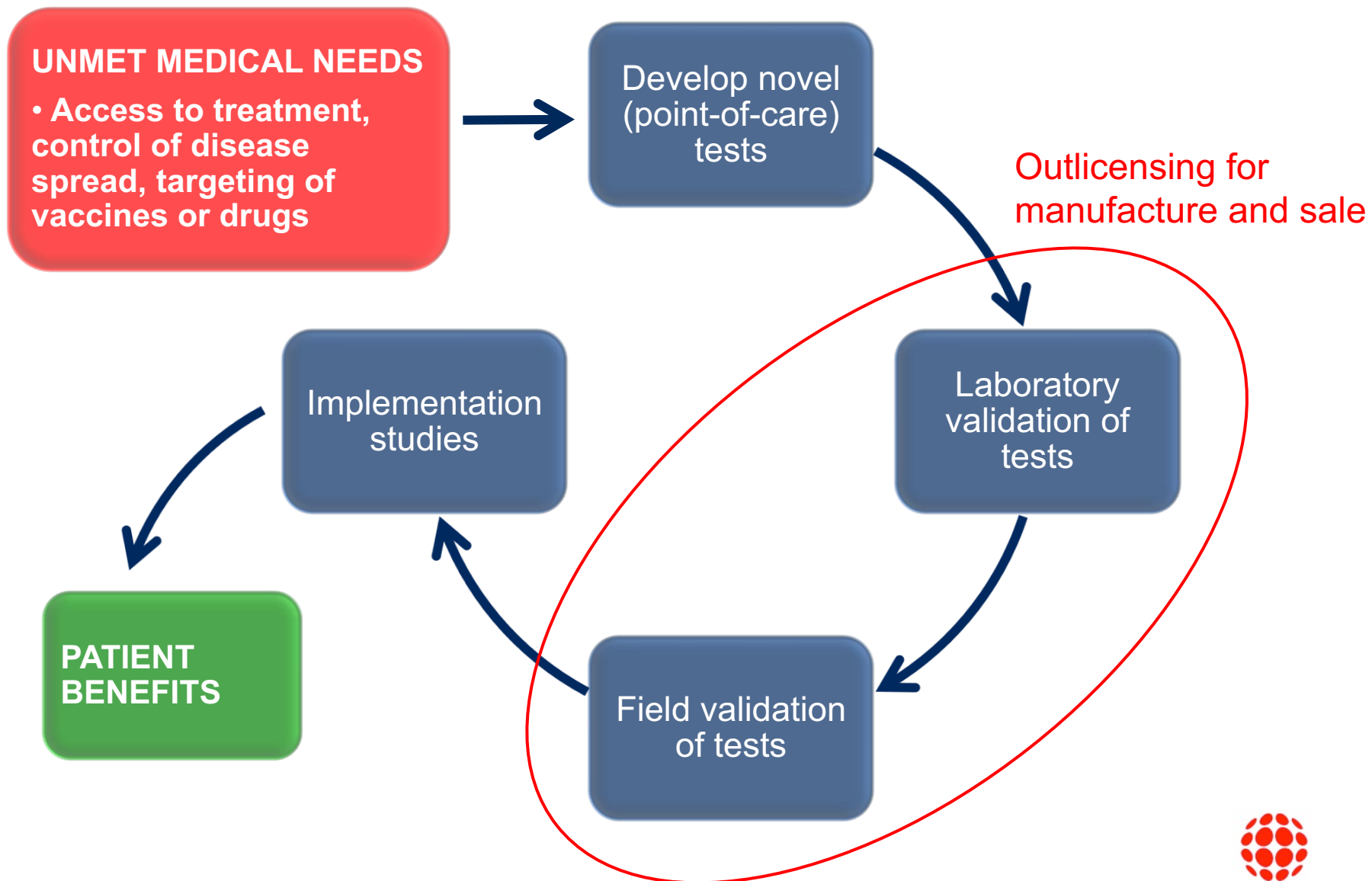


PATIENT
BENEFITS



Burnet Hepatitis E test in field use.

Priority Diagnostics Roadmap



Test commercialisation

Hepatitis E IgM



Visitect CD4 (HIV)

SAVING
LIVES
AT BIRTH:



Visitect Syphilis IgA

SAVING
LIVES
AT BIRTH:
A GRAND CHALLENGE
FOR DEVELOPMENT



Pushing the boundaries of lateral flow

- An alternative to Flow Cytometry
 - CD4 T-cells in HIV (Visitect CD4); neutrophil CD64/NE in sepsis
- An alternative to enzymatic tests
 - Alanine aminotransferase (ALT) in liver disease
- An alternative to centrifugation
 - Plasma separation for HIV viral load (and molecular tests)
- Novel biomarkers
 - Treponemal IgA for confirmation of active syphilis
 - Dimeric IgA as a marker of acute mucosal infections (incl. hepatitis)

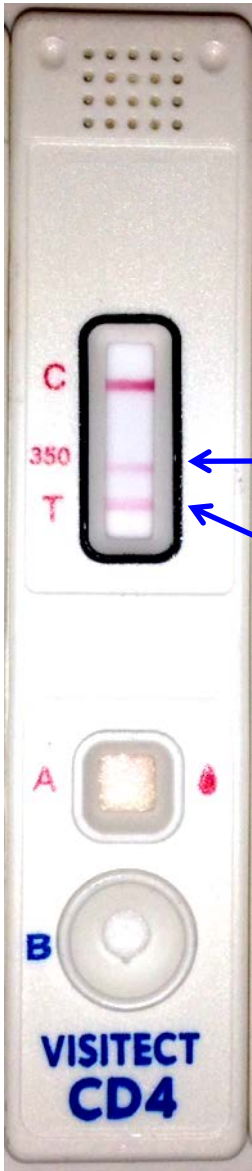
Neutrophil CD64 in sepsis

- Sepsis kills around 8 million people each year, mostly neonates and young children plus the elderly
- Urgent need for rapid diagnosis to identify severe infections requiring antibiotic treatment, while reducing over-treatment of those with similar signs/symptoms (fever)
- Adaptation of the neutrophil CD64 index test (Leuko64) to point of care using the same approach as CD4
 - But surprising discovery along the way....
- Clinical study of novel biomarkers (lab-based ELISAs) in healthy controls and sepsis patients, Alfred Hospital ICU (ongoing)



Axxin - Instrumentation for POC quantitation

A

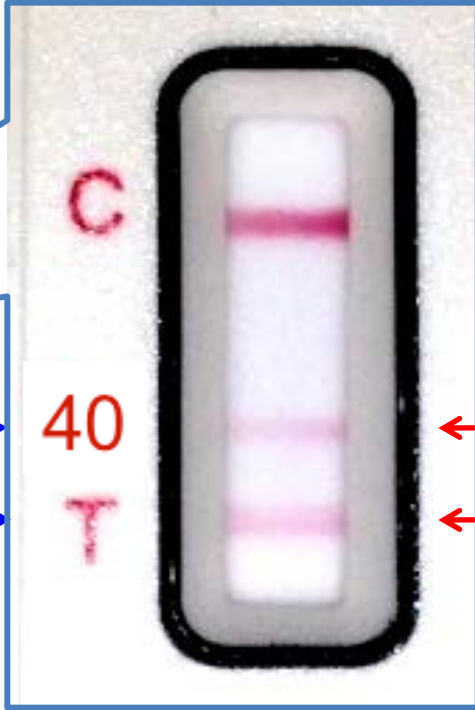


350
C
T

350 reference
CD4 Test line

B

Procedural control




C
40
T

Alanine aminotransferase (ALT) test

Reference (40 U/L)
ALT test line

C

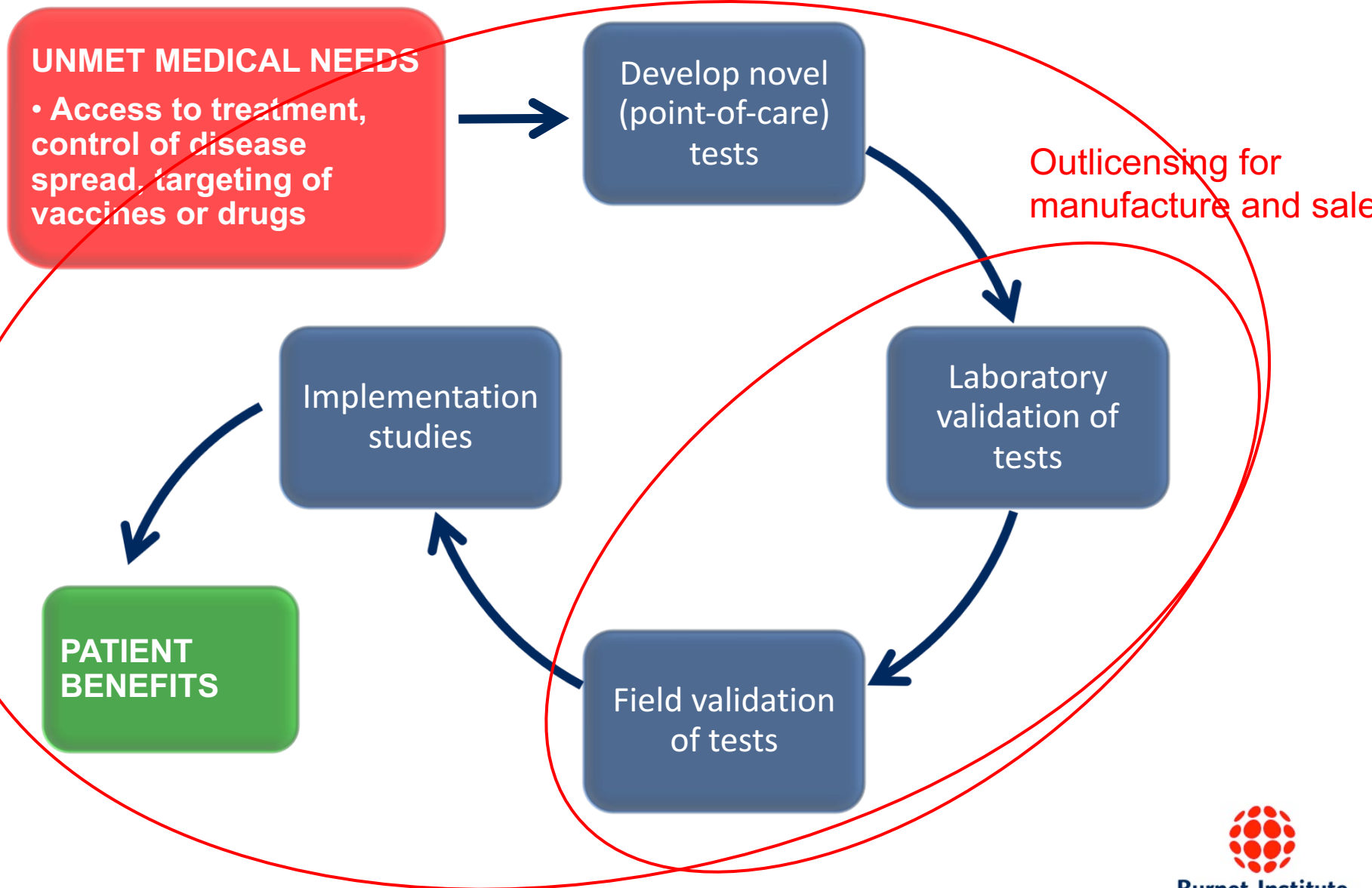


INTERPRETATION:

Test line \geq reference = liver disease

Test line $<$ reference = not liver disease

Priority Diagnostics Roadmap



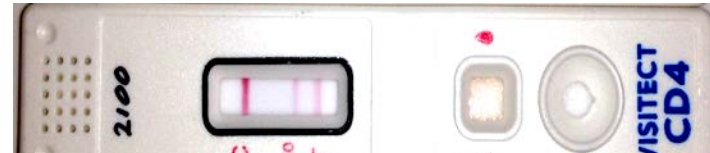
Commercialisation (2)

Hepatitis E IgM



Visitect CD4 (HIV)

SAVING
LIVES
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Visitect Syphilis IgA

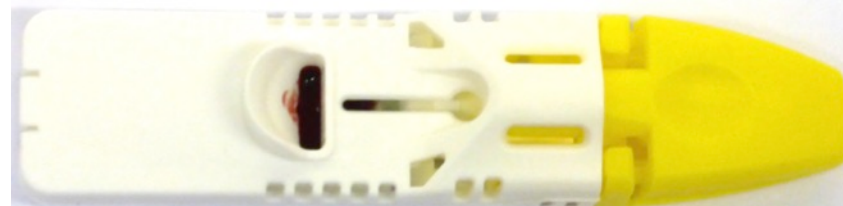
SAVING
LIVES
AT BIRTH:



BioPoint Liver



BioPoint VL-Plasma



Burnet in China – Building on 20 years....

- **Nanjing BioPoint Diagnostic Technology Co. Ltd.**
- Wholly foreign-owned entity (WFOE), established in 2013 with 321 grant in Jiangsu Life Science Technology and Innovation Park
 - ~\$240,000 from Nanjing Government, plus ancillary support
 - 12.5 million RMB (≈2.5M \$A) Chinese investment 2014
- Development and commercialisation of point-of-care diagnostic tests for China and global markets in areas of **unmet medical need, starting with ALT test (liver disease) and VL-Plasma (plasma separator)**



南京澳百生物技术有限公司
Nanjing BioPoint Diagnostics



Burnet Institute
Medical Research. Practical Action.

Jiangsu Life Science Technology and Innovation Park, Nanjing



Nanjing BioPoint – GMP facility

