Advances in point of care testing

Dr Elsie Williams

Burnet
reach for the many

At Burnet Institute, we proudly acknowledge the Boon Wurrung people of the Kulin Nations as the Traditional Custodians of the land on which our office is located. We pay our respect to Elders past and present, and extend that respect to all First Nations people.

Conflict of interest

I, Elsie Williams, am an inventor on the syphilis point-of-care test, which is the subject of PCT patent application PCT/AU2025/050155. The Burnet Institute, my employer, is co-developing the commercial product with Atomo Diagnostics and has licensed the technology to Atomo. As a result, both the Burnet Institute and I may benefit from the commercial development and licensing of this technology.

Burnet Diagnostics Initiative (BDI)

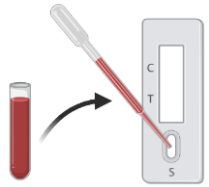
Innovate → **Validate** → **Translate**

- Biomarker discovery & protein engineering
- Antibody-ligand and protein-protein interactions
- Lateral flow technology
- Assay design and development
- Assay verification

- Analytical studies
- Clinical studies
- User acceptability studies

bsi ISO 9001 Quality Management Systems CERTIFIED

- Prototype development
- Market development
- Technology transfer
- Licensing



BDI: Two POCT relevant to Triple elimination

Burnet ALT test:

Monitoring tool for hepatitis B

Dr Lilian Hor
Session 5A, Friday 12:30 pm
Development of a rapid point-of-care self-test for liver damage

Active Syphilis Rapid test:

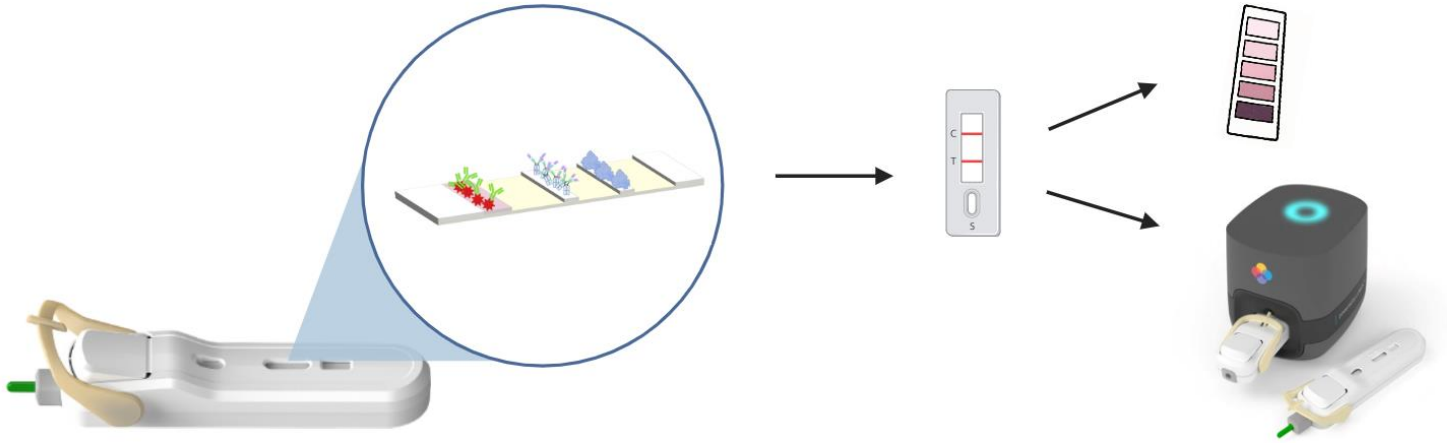
Diagnosis of active syphilis

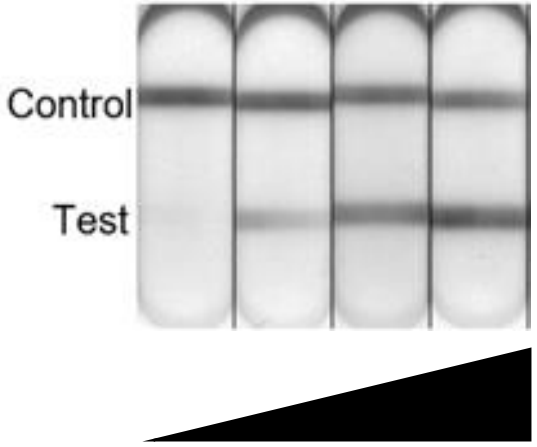
Bridging the gap: an accessible means to assess liver health

ALT levels are a key biomarker for **liver health**

In **low-resource settings** or **remote** areas access to pathology services can be difficult

Point of care testing for ALT would deliver quick, on-site results and **improve how disease is managed**





ALT1

ALT POCT for Hepatitis B

Monitoring liver health in known HBV-positive pregnant women

WHO 2024 HBV recommendations: Who to treat?

Treatment is recommended for **all adults and adolescents** (aged ≥12 years) with chronic hepatitis B (including pregnant women and girls and women of reproductive age) with:

1. **Evidence of significant fibrosis** (≥ F2) based on an APRI score of >0.5 or transient elastography value of >7 kPa or evidence of cirrhosis (F4) based on clinical criteria, regardless of HBV DNA or ALT levels.

OR

2. **HBV DNA >2000 IU/mL and an ALT level above the upper limit of normal** (ULN) (30 U/L for men and boys and 19 U/L for women and girls). For adolescents, this should be based on ALT>ULN on at least two occasions in a 6- to 12-month period.

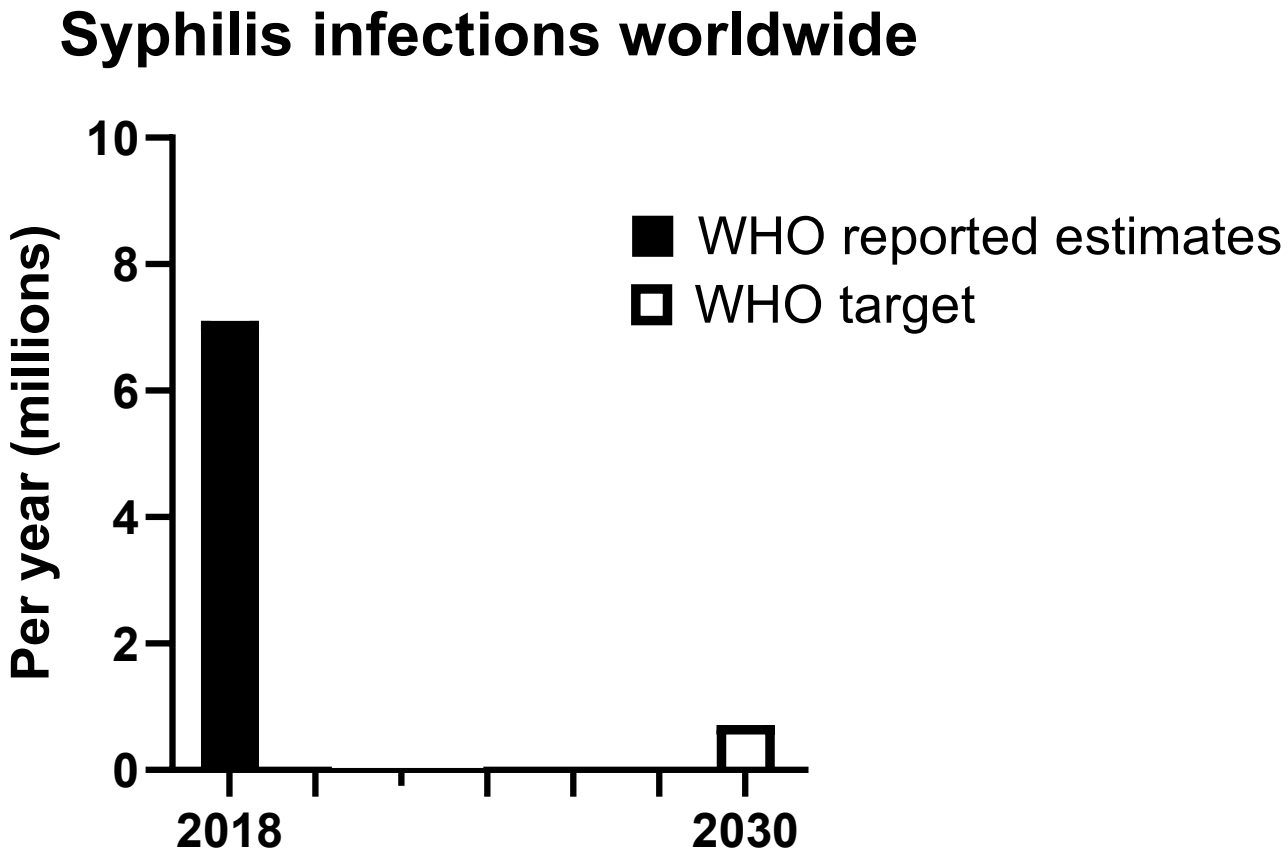
OR

3. **Presence of coinfections** (such as HIV, hepatitis D or hepatitis C); **family history of liver cancer or cirrhosis; immune suppression; comorbidities; or extrahepatic manifestations**, regardless of the APRI score or HBV DNA or ALT levels.

OR

4. **In the absence of access to an HBV DNA assay: Persistently abnormal ALT levels alone** (defined as two ALT values above the ULN at unspecified intervals during a 6- to 12-month period), regardless of APRI score.

Syphilis is staging a comeback globally

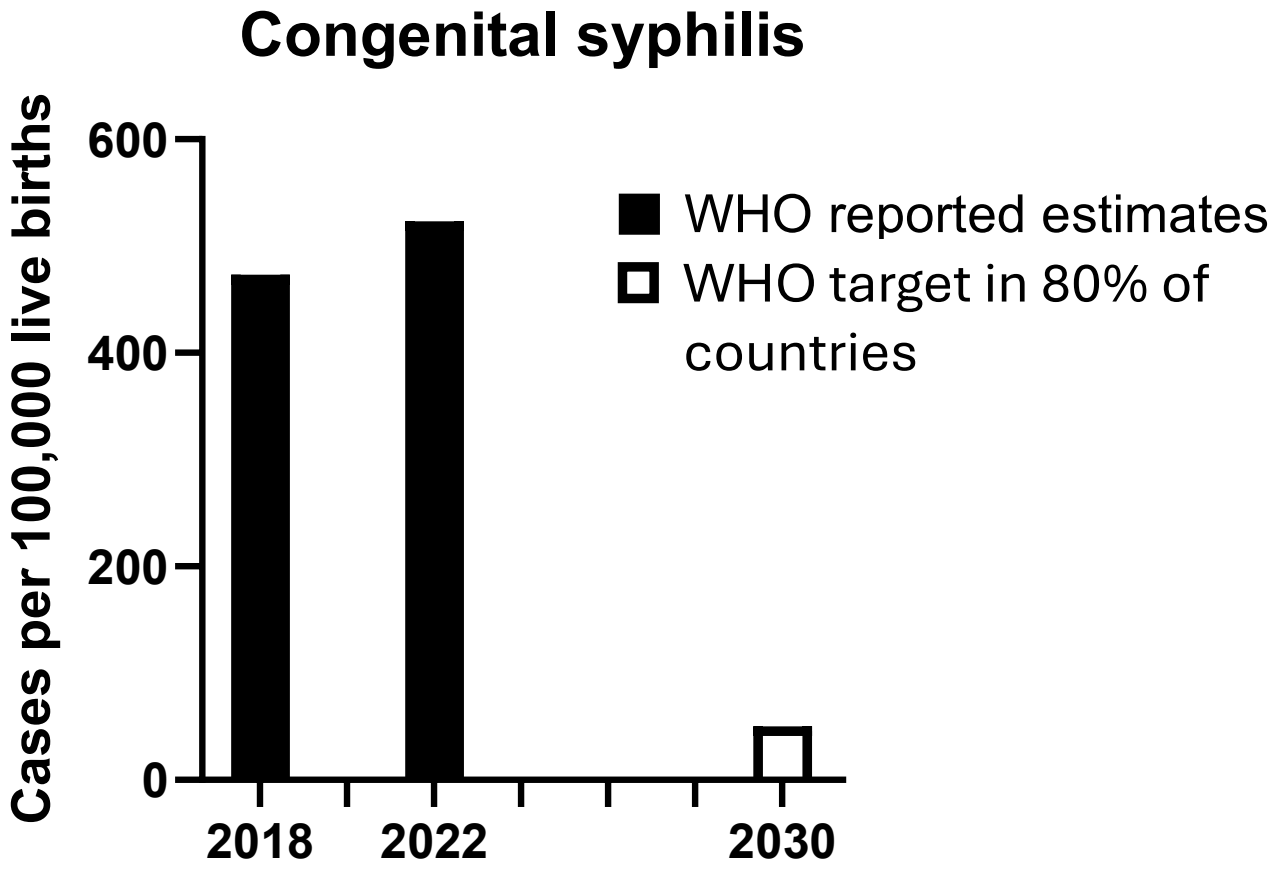


Sexually and vertically transmitted bacterial infection caused by *Treponema pallidum*

Can be cured by injections of Benzylpenicillin

Women with syphilis who are untreated have a 50-80% chance of an adverse birth outcome

Syphilis is staging a comeback globally



WHO global research priorities for sexually transmitted infections[1]:

"Develop low-cost, rapid STI point-of-care tests: to distinguish active syphilis from latent or past infection"

In 2022 syphilis caused ~220,000 estimated neonatal, early fetal and still births

1) Gottlieb, S. L., et al. (2024) Lancet Glob Health 12;9

Why point-of-care tests?

"Develop low-cost, rapid STI **point-of-care tests**: to distinguish active syphilis from latent or past infection"

Centralised laboratory diagnosis:

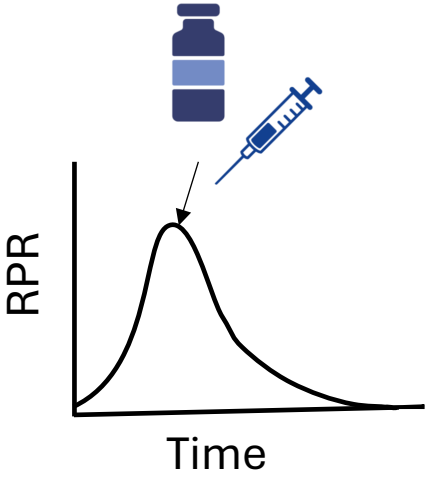
Treponemal test 1

Treponemal test 2

Treponemal tests stay positive post cure

Non treponemal e.g. RPR Test

Not syphilis specific



· Resource intensive · Loss to follow up

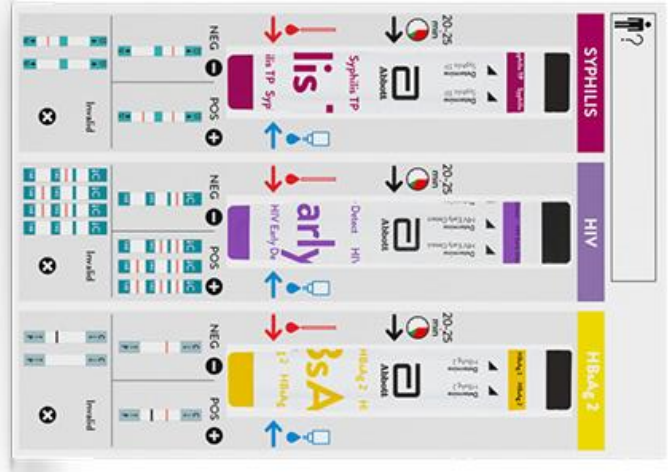
Why **active** vs past-treated?

"Develop low-cost, rapid STI point-of-care tests: to distinguish **active** syphilis from latent or **past infection**"

The are >10 approved syphilis POCT with good sensitivities and specificities (typically 90-99%) for detecting **ever infected** from **never infected.**

WHO prequalifies the first triple diagnostic test for HIV, hepatitis B and syphilis, a milestone toward global disease elimination goals

15 July 2025 | Departmental update | Geneva |Reading time: 2 min (611 words)



WHO prequalified syphilis tests: lateral flow tests for **treponemal antibodies** → stay positive post successful treatment

Why **active** syphilis vs past-treated?

Use of existing POCT >>>> No testing, particularly in antenatal care

· Expands testing · Test and treat models · Self-test

↑ Syphilis prevalence

↑ False positives

Overtreatment

↑ People who can't be offered point of care testing

Overtreatment

- Periodic shortages of benzathine penicillin
- Potentially increases risk of resistance (resistance to azithromycin has already occurred)

Why **active** syphilis vs past-treated?

Rates of past treated vs active infection will differ hugely between geographical regions, and key populations

Report on syphilis tests performed 2022-2023 by a London based Sexual Health service as part of a mail order STI screening panel[1]

1) Day, S. L., et al. (2025) Sex Transm Infect. 19;101(4):242-246

Why **active** syphilis vs latent?

"Develop low-cost, rapid STI point-of-care tests: to distinguish **active** syphilis from **latent** or past infection"

With time, many latent patients' serology = past treated patients' serology
(TP positive, RPR non-reactive)

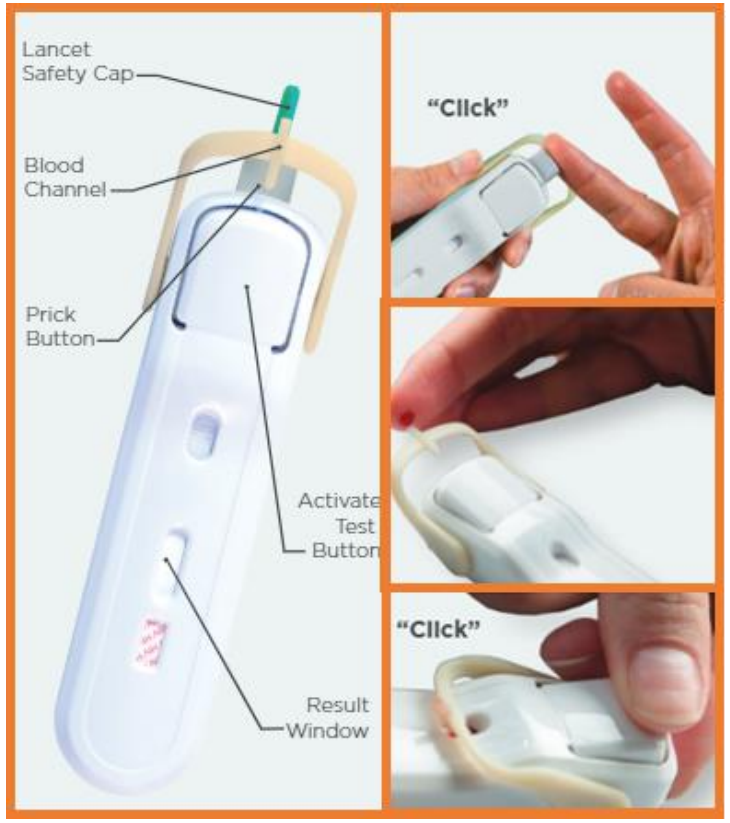
	Primary	Secondary	Latent	
Time post exposure	~3 weeks	~6 weeks -6 months	6 months-2 year	2 years+
Symptomatic	Yes	Yes	No	
RPR	Increasing	High	Decreases	Becomes non-reactive
Infectious to sexual partners	Yes	Yes	Decreases	No
Infectious to fetus	Yes	Yes	Decreases	

For epidemiological control, finding active patients is sufficient. Still risk of vertical transmission.

Lateral flow point-of-care test for active syphilis

Still a treponemal test, but using **specific TP antigens** and just measuring **IgA antibodies** improves past-treated specificity

AtomoRapid™ Pascal cassette



WHO TPP	Optimal	Test performance
Time to result	≤15 mins	15 mins
Specimen	Fingerprick max 20 µL	10 µL
Specimen preparation	Integrated	
Steps between specimen preparation and result	One operator step, no timed interval	

Combined clinical sample panel

Active syphilis

Current POCT positives

Clinical status	Untreated syphilis (49)		Past treated* (36)		Never infected (525)
Treponemal assay		Positive			Negative
RPR	Reac. (45)	Non Reac. (4)	Reac. (6)	Non Reac. (30)	Not performed

*>3-month post diagnosis of last infection

MSHC MELBOURNE SEXUAL HEALTH CENTRE

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Sensitivity and specificity

Active Syphilis POCT

Population	Sensitivity (n/N)	Specificity (n/N)
Untreated	93.9% (46/49)	
Active	**100.0% (45/45)**	

Determine™ Syphilis TP

Sensitivity (n/N)	Specificity (n/N)
100.0% (38/38)	
-	
	94% (16/17)
	0% (0/36)
	-

Would be overtreating 36 people, instead of 6

Conclusions

BDI is developing two POCT relevant to triple elimination

- for ALT levels to monitor liver health
- detect active syphilis

Ongoing work

Expanding active and past-treated syphilis patient samples

Progressing clinical studies of both the syphilis and ALT tests to validate performance with fingerprick blood

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