

FIND 

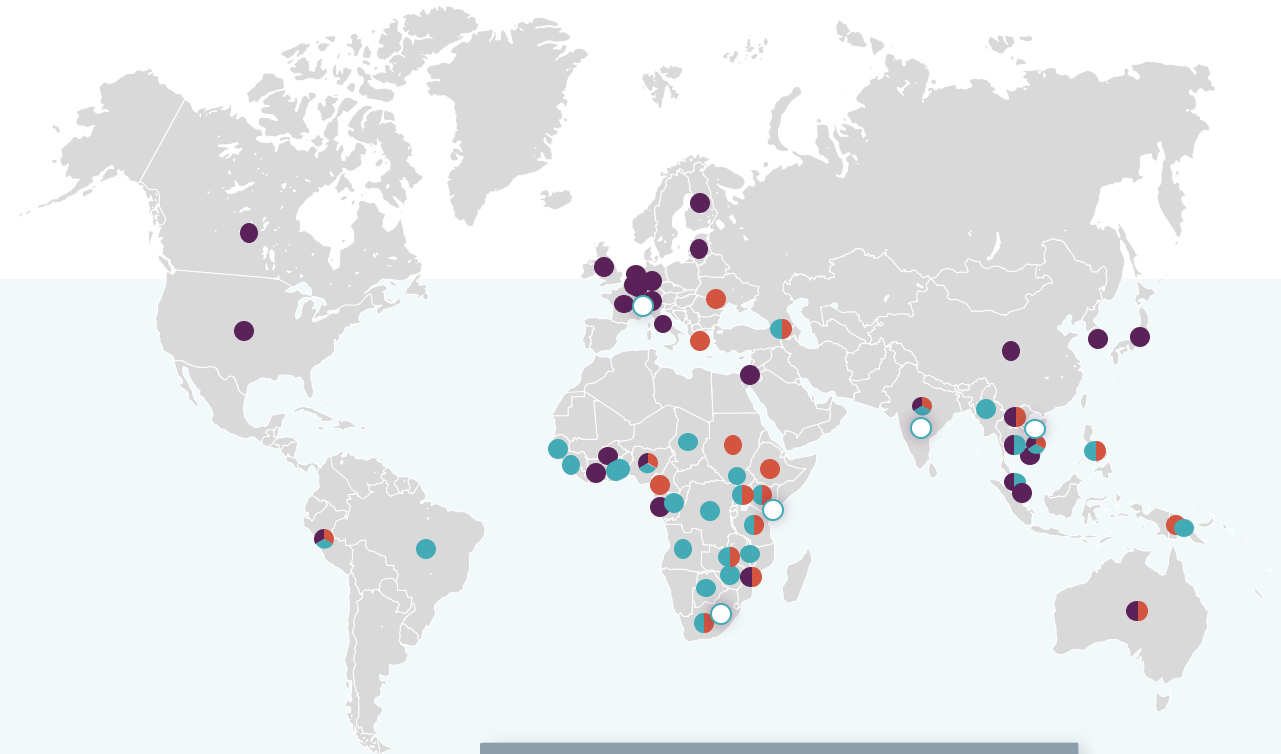
STI POC DIAGNOSTICS

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FIND, THE GLOBAL ALLIANCE FOR DIAGNOSTICS, SEEKS TO ENSURE EQUITABLE ACCESS TO QUALITY DIAGNOSIS AROUND THE WORLD

We connect countries and communities, funders, decisionmakers, healthcare providers and developers to spur diagnostic innovation and make testing an integral part of **sustainable, resilient health systems**



Projects			
● R&D	● Clinical trials	● Access	 Offices

- ◆ Established in 2003 as a product development & delivery partnership
- ◆ Co-convener of the Access to COVID-19 Tools (ACT) Accelerator Diagnostic Pillar
- ◆ WHO Collaborating Centre for Laboratory Strengthening & Diagnostic Technology Evaluation
- ◆ WHO SAGE-IVD member

POC STI DIAGNOSTICS

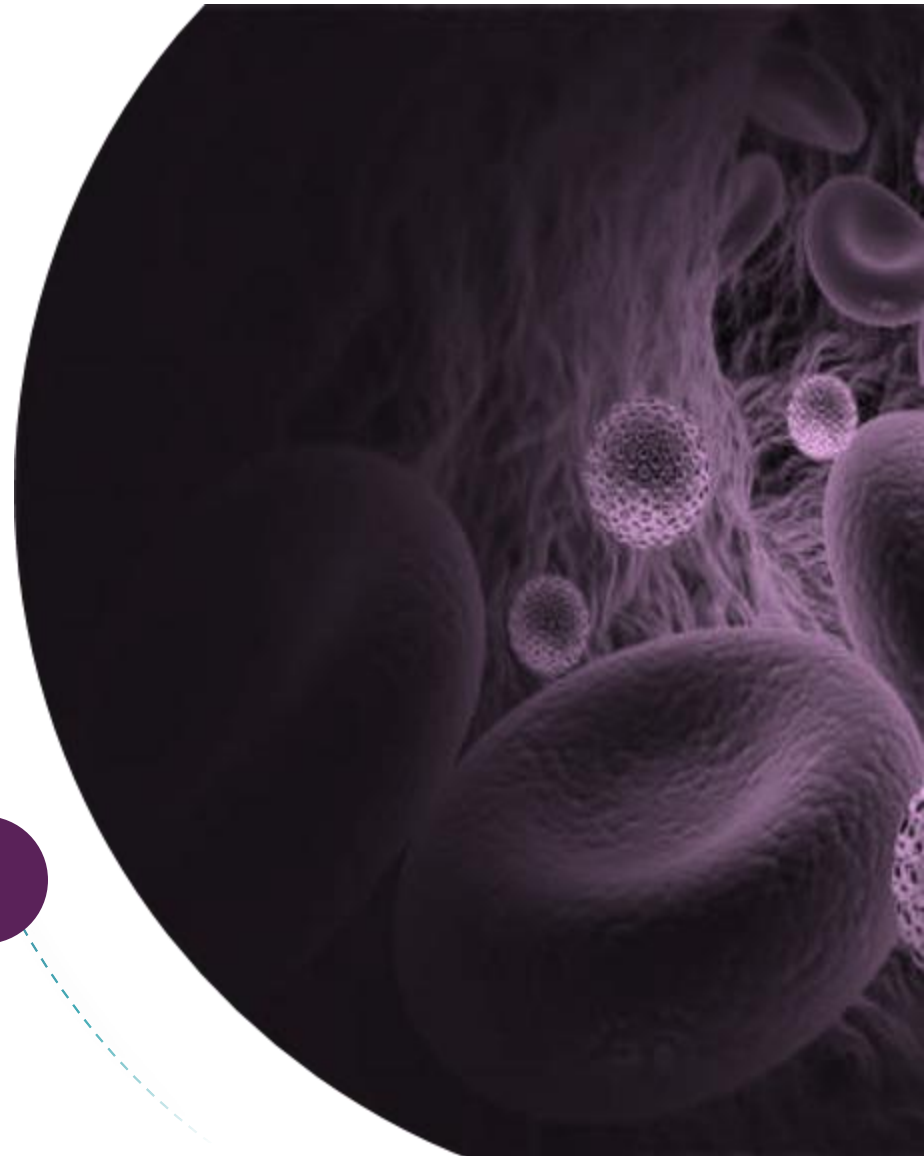
FIND Lateral Flow Assay

Identification of NG and guide antibiotic treatment



POC molecular NG/CT Tests

New LMIC opportunities for multiplex molecular platforms

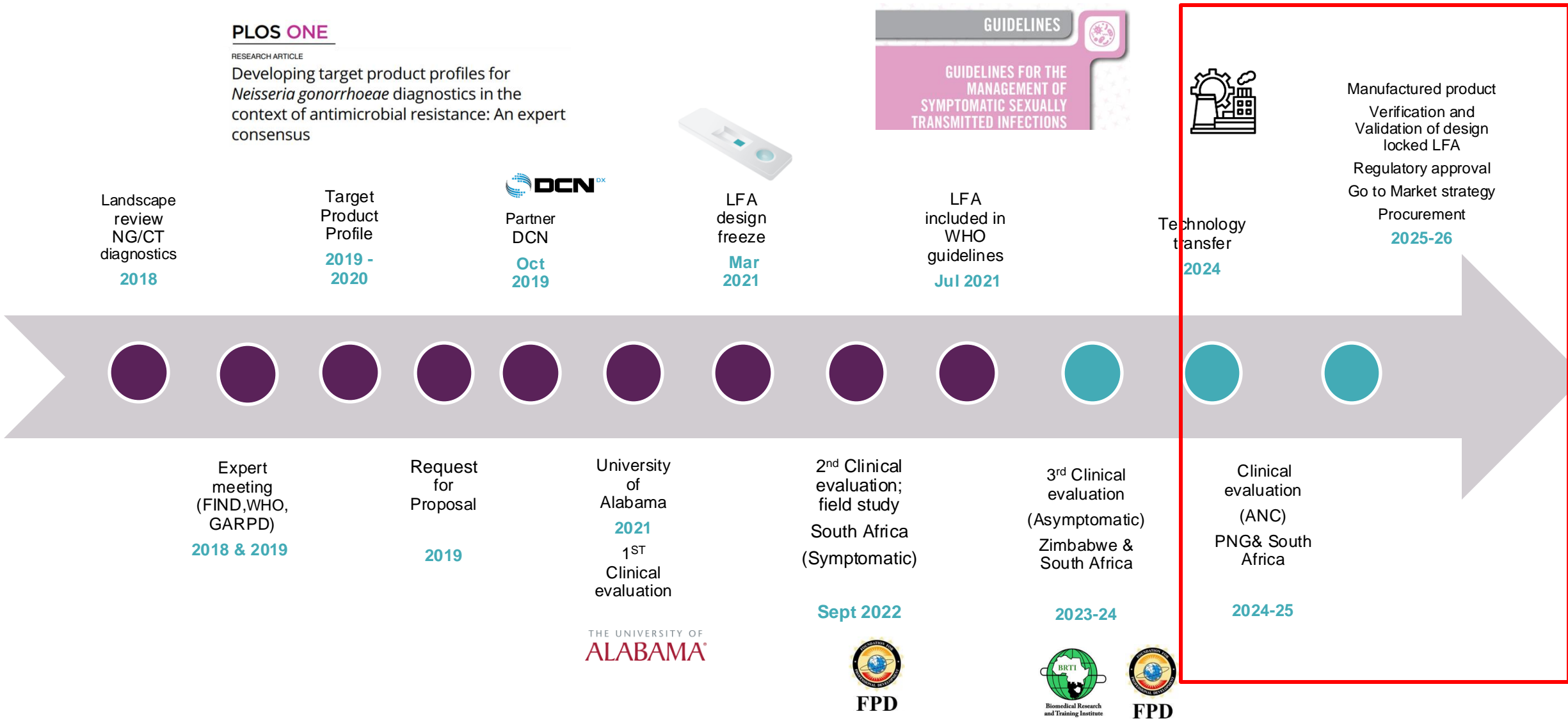
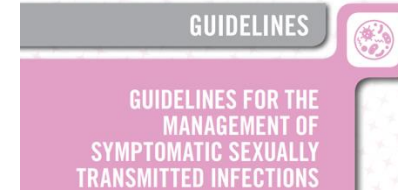


FIND NG LFA ASSAY DEVELOPMENT 2018-2026

PLOS ONE

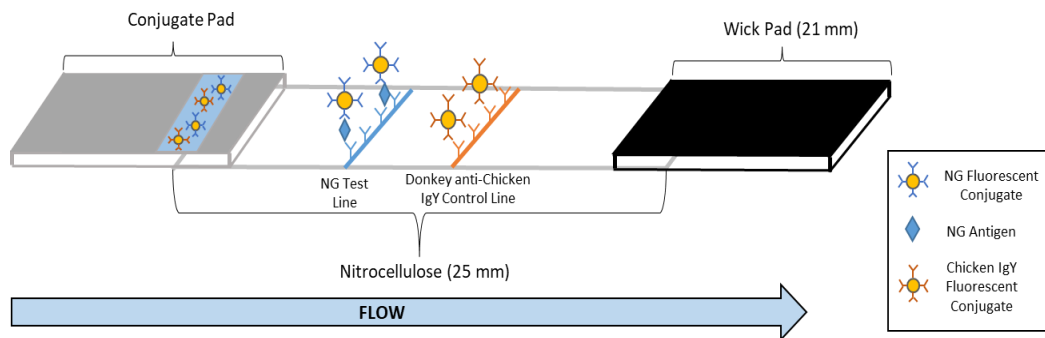
RESEARCH ARTICLE

Developing target product profiles for *Neisseria gonorrhoeae* diagnostics in the context of antimicrobial resistance: An expert consensus



DEVELOPMENT OF THE FIND NG LFA

Lateral flow design:



Gleeson B, et al. Development of a Novel Fluorescent-Based Lateral Flow Assay for the Detection of *Neisseria gonorrhoeae* at the Point of Care. *Sex Transm Dis.* 2024 Mar 1;51(3):186-191.
https://journals.lww.com/stdjournal/fulltext/2024/03000/development_of_a_novel_fluorescent_based_lateral.8.aspx

FIND has developed a 20-minute, easy to run, POC assay for detection of *N. gonorrhoeae* for **female vaginal swabs and male urine**

Antigen target: Outer membrane protein

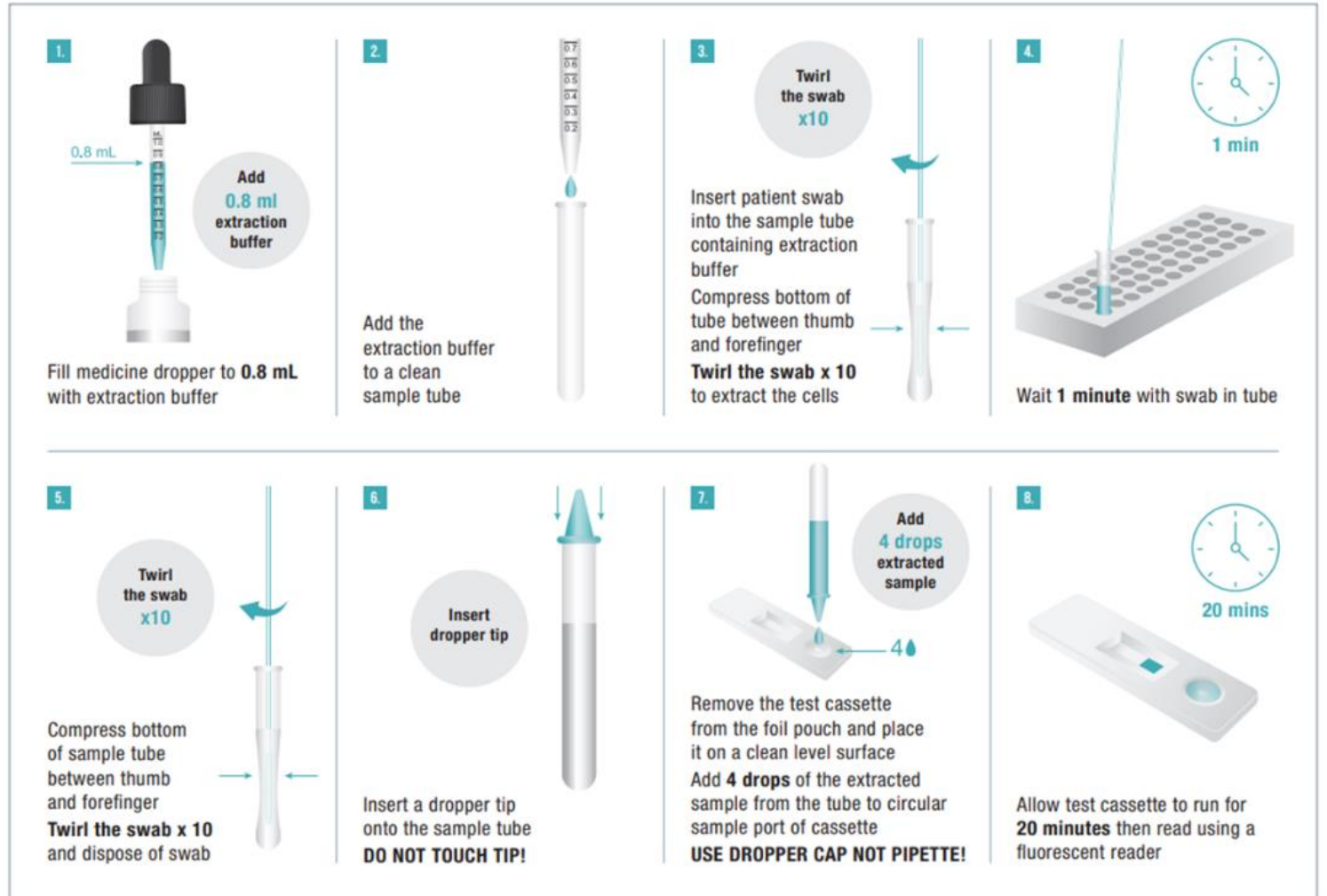
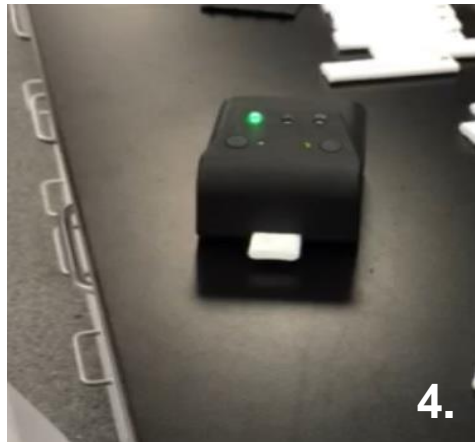
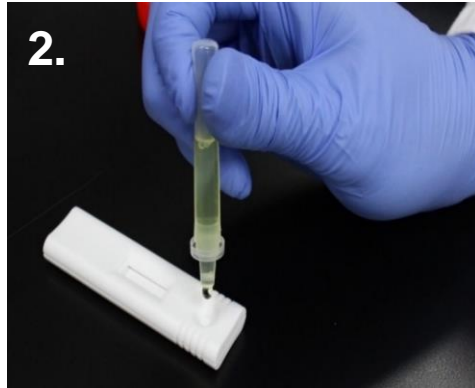
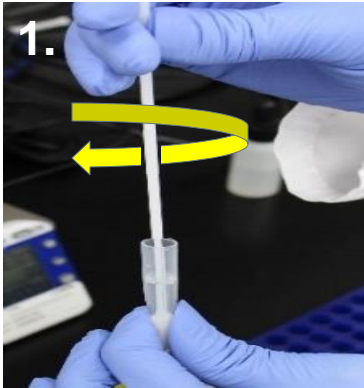
Analytical sensitivity (LOD): $1 \times 10^3 - 5 \times 10^3$ CFU/mL depending upon NG reference strain

Inclusivity: 31 NG strains (ATCC, NCTC, WHO, ZeptoMetrix), all NG strains detected between 1 and 1×10^5 CFU/mL.

Cross-reactivity: 21 non-*Neisseria* pathogens/microorganisms negative; 10 *Neisseria* species: cross-reactive with *N. meningitidis*, *N. lactamica*, *N. polysaccharea*

Stability: Shelf-life min. 1 year @ 40C/70%RH

CLINICAL EVALUATION IN SYMPTOMATIC PATIENTS IN SOUTH AFRICA



CLINICAL EVALUATION AMONG SYMPTOMATIC PATIENTS IN SOUTH AFRICA



Symptomatic men		Symptomatic women	
Prevalence: 64%		Prevalence: 18%	
Sensitivity	96% (91% – 98%)	Sensitivity	92% (78% – 97%)
Specificity	97% (90% – 99%)	Specificity	96% (92% – 98%)

	Minimal requirement	Optimal requirement
Sensitivity	>80%	>90%
Specificity	>95%	>98%
Time to result	≤ 30 minutes	≤ 10 minutes

CLINICAL EVALUATIONS AMONG ASYMPTOMATIC AND ANC POPULATIONS



Asymptomatic men (S. Africa)

Prevalence: 6.2%

Sensitivity 81% (64% – 91%)

Specificity 94% (92% – 96%)

Asymptomatic women (S. Africa)

Prevalence: 8.3%

Sensitivity 82% (66% – 91%)

Specificity 98% (96% – 99%)

Pregnant women (Zim, ANC)

Prevalence: 4.2%

Sensitivity 66% (49% – 80%)

Specificity 99% (99% – 100%)

WHAT NEXT?

NG LFA

- ◆ Technology transfer ongoing negotiations with potential manufacturers
- ◆ Regulatory pathway and go-to-market strategy
- ◆ Evidence generation for NG LFA
 - Other geographies and population sub-groups (e.g. symptomatic and asymptomatic key populations)
 - Pilot for self-collection
 - Pilot for extragenital samples
 - Usability and acceptability
 - Modelling of impact and cost-effectiveness
 - Studies to demonstrate impact, cost-effectiveness (in 2026 and after)
- ◆ CT LFA feasibility

NG/CT Molecular

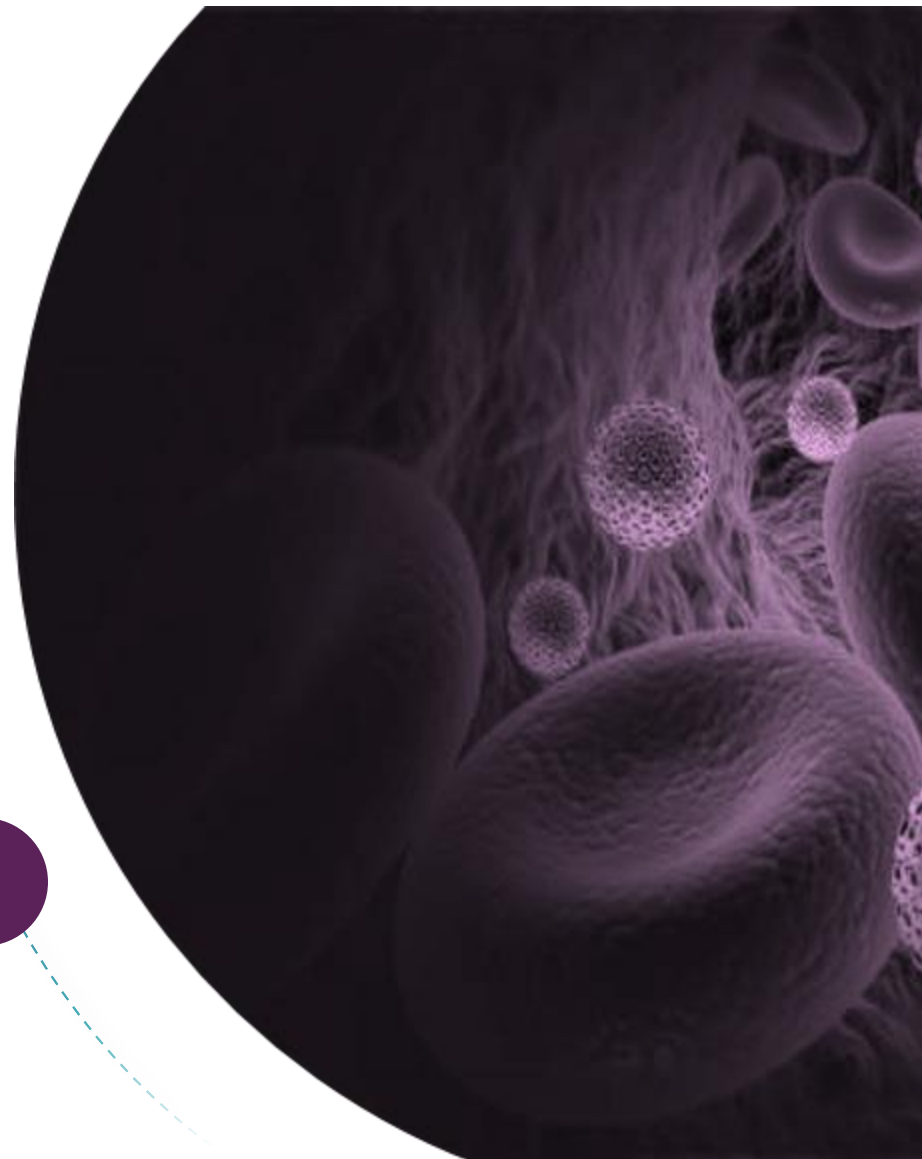
- ◆ low-cost NG/CT molecular POC assay

POC STI DIAGNOSTICS

FIND Lateral Flow Assay
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POC molecular NG/CT Tests
 New LMIC opportunities for multiplex molecular platforms



MOLECULAR PIPELINE FOR NG TESTS

MANY COMPANIES ANNOUNCED DEVELOPMENT OF POC STI MOLECULAR TESTS



Request for Proposals

Seeking manufacturers of true point-of-care molecular tests for *Neisseria gonorrhoeae* and *Chlamydia trachomatis* to accelerate product development/evaluation and market entry in low- and middle-income countries.

visby medical™



Detect



Scout™



novel
MICRODEVICES



Sherlock
BIOSCIENCES



MAGIC
LIFESCIENCE



aptitude



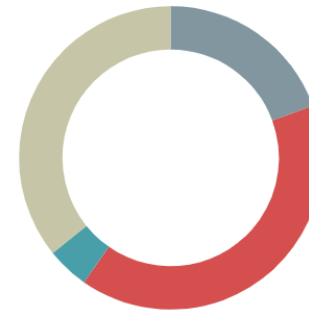
self
diagnostics

NG POC DX PIPELINE – FIND TEST DIRECTORY

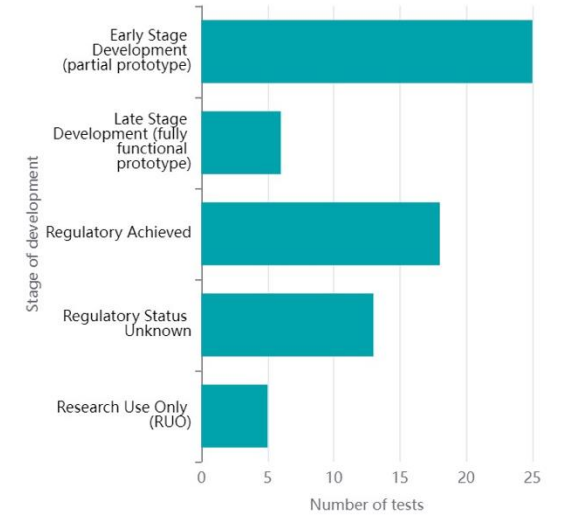


Region of manufacturer HQ

- European Region
- Region of the Americas
- South-East Asian Region
- Western Pacific Region

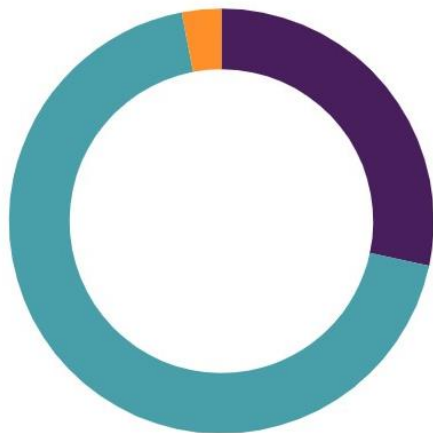


Stage of development

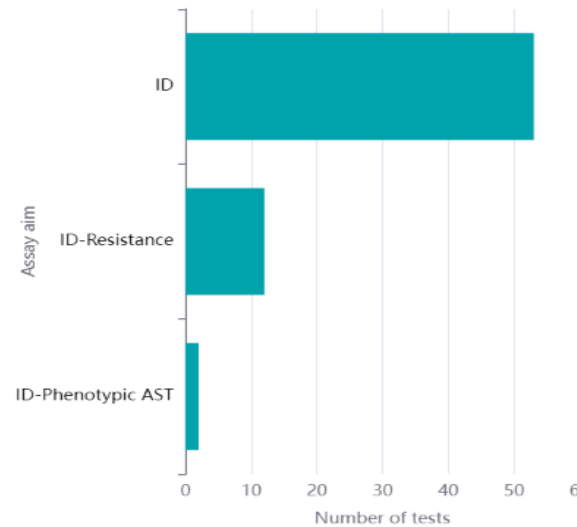


Type of technology

- Immunoassay
- Molecular
- Biophysics



Assay aim



True vs near POC

- True POC
- Near POC



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THANK YOU

FIND 
Diagnosis for all

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