

# Is South Africa ready for non-sputum, point-of-care TB diagnostics? (DriveDx4TB)

*Assessing end-user insights on novel tests using alternative sample types for TB diagnosis*

*Ms Nasiphi Ntombela SA TB Conference, June 2024*

## Introduction

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- Objective 3 of National Strategic Plan to end HIV, TB and STIs for 2023-2028
  - Strengthen TB diagnosis and support for people with TB
  - Accelerate the scale up of innovative processes, diagnostic tools and regimens for the diagnosis, treatment, and care for people with TB
  
- Alternative samples types needed to improve access to TB testing

## Why assess end-user insights?



Decisions about TB diagnostics have historically been made without adequately engaging end-users (patients and healthcare providers)



Pre-empt barriers to implementation at the development stage which will enable better scale-up and adoption for National TB programmes.



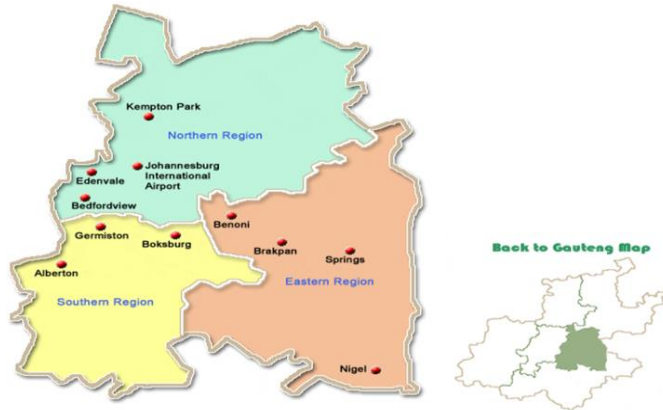
Limited evidence about acceptability of novel sample types for TB diagnostics



DriveDx4TB Started with the END in mind!

# Where did we conduct this study?

Ekurhuleni District - 8 Clinics



Bojanala District - 8 Clinics



## Study method and population



### QUANTITATIVE Surveys



TB care recipients (n=154)  
Group 1 – Timely TB Diagnosis & Linkage  
Group 2 – Without Timely TB Diagnosis & Linkage



Health care workers  
(n=102)



Civil Society stakeholders  
(n=20)



Public health experts  
(n=20)



### QUALITATIVE Semi-structured interviews (SSI)



Health care workers  
(n=11)



Civil Society stakeholders  
(n=5)

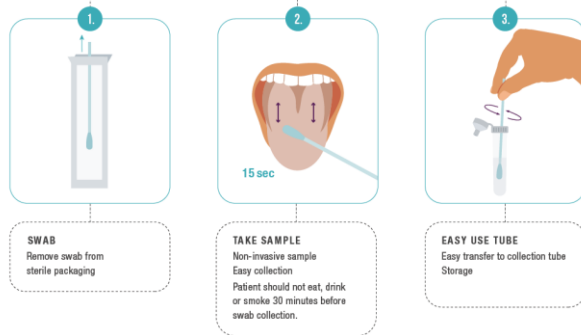


Public health experts  
(n=5)

# Visual information sheets: TB Care Recipients

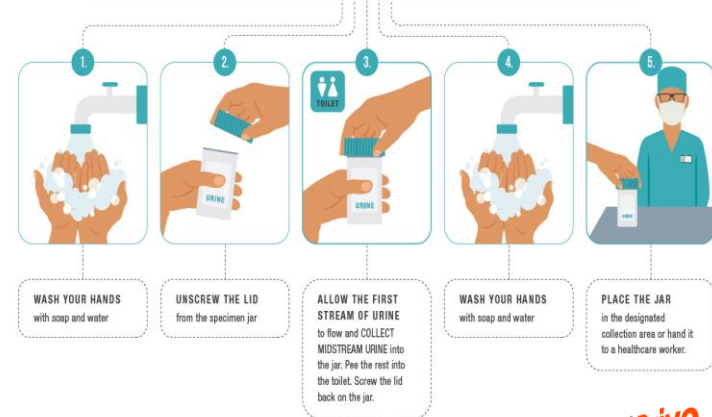
## TONGUE SWAB COLLECTION

To provide a tongue swab sample you would need to follow the instructions as below:



## URINE - VISUAL INSTRUCTION SHEET (FOR PATIENTS)

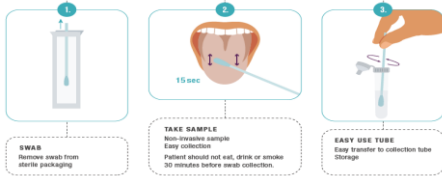
To provide a urine sample, go to a toilet facility in the health clinic and follow the instructions as below:



# Visual information sheets: HCW, CS, PHE

## TONGUE SWAB COLLECTION

To provide a tongue swab sample you would need to follow the instructions as below:



Price range:

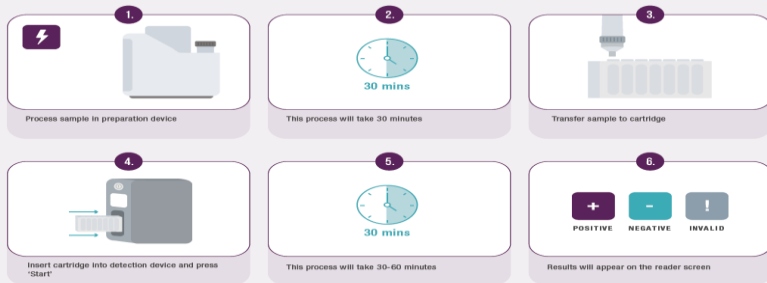
On existing technology: for the sample ca. R3,74 - R 5,60

For true POC: for the sample and test: R93,38 - R149,42

Negotiations are still ongoing with the manufacturers on prices

## TONGUE SWAB SAMPLE PREPARATION AND TESTING

Sample preparation, loading on the cartridge and read in the device

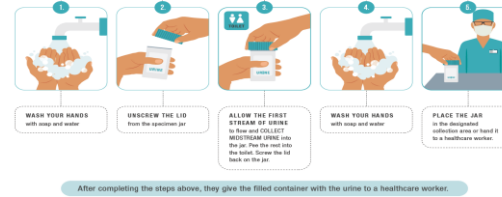


Performance: It is expected that the performance of the tongue swab on existing molecular technology (existing platforms that can run the test such as GeneXpert and M200) and any true point of care will be similar.

Sensitivity: around 70% (still being evaluated)  
Specificity: around 98% (still being evaluated)

## URINE - VISUAL INSTRUCTION SHEET (FOR HEALTHCARE WORKERS)

To provide a urine sample, the patients goes to a toilet facility in the health clinic and follows the instructions as below:



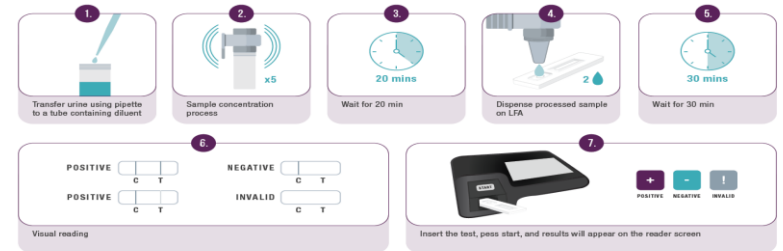
After completing the steps above, they give the filled container with the urine to a healthcare worker.

Price range: R56,08 - R93,38

The price is currently being negotiated with manufacturers

## URINE - VISUAL INSTRUCTION SHEET (FOR HEALTHCARE WORKERS)

The healthcare worker will take the urine sample to prepare it and complete the test:



It is estimated that the time to complete the test by the healthcare worker takes 20 to 30 minutes.

Performance: We are speaking of next-generation tests using urine samples, not the performance of any current tuberculosis test that uses urine sample, as we know that the current tests do not have high sensitivity when testing the general population.

Sensitivity of next-generation tests using urine sample: >65%  
Specificity of next-generation tests using urine sample: 99%

## Hearing from the end users

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(PH, 51, Woman, Urban & Rural)

*“...starting [TB] treatment depends on the test, how fast the test is and how effective [accurate] the test is, then we'll start treatment. So, if tests are easier and manageable, the issue of starting treatment will be easy. If I diagnose now, I [can] start treatment right now and that will be made possible by these [novel] tests”*

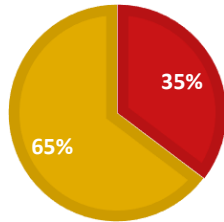


# TB care recipients and healthcare worker perceptions | Experience providing sputum

Did you find it difficult to give the sputum sample?

## TB CARE RECIPIENTS

■ Yes ■ No



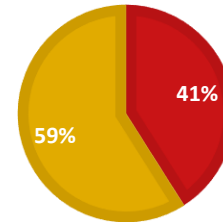
Difficulties to cough, no sputum, feeling uncomfortable, embarrassed, fear of the results  
Comfortable, no difficulties...



Is it difficult for clients to give the sputum sample?

## HEALTHCARE WORKERS

■ Yes ■ No



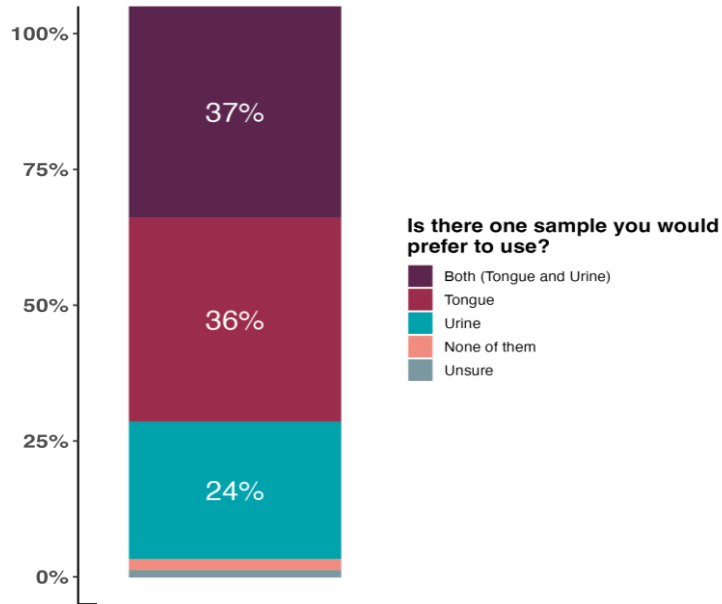
“Some patients do not have sputum”



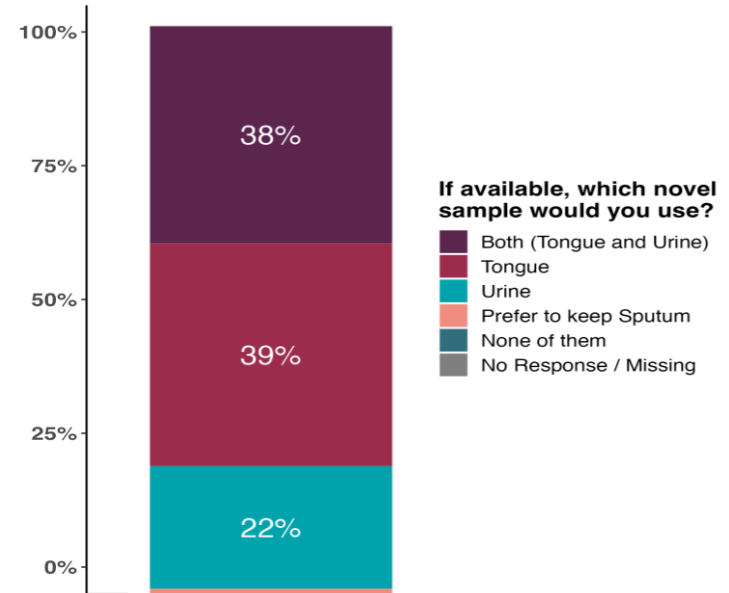
# Preferences and acceptability of novel sample types



## TB service recipients



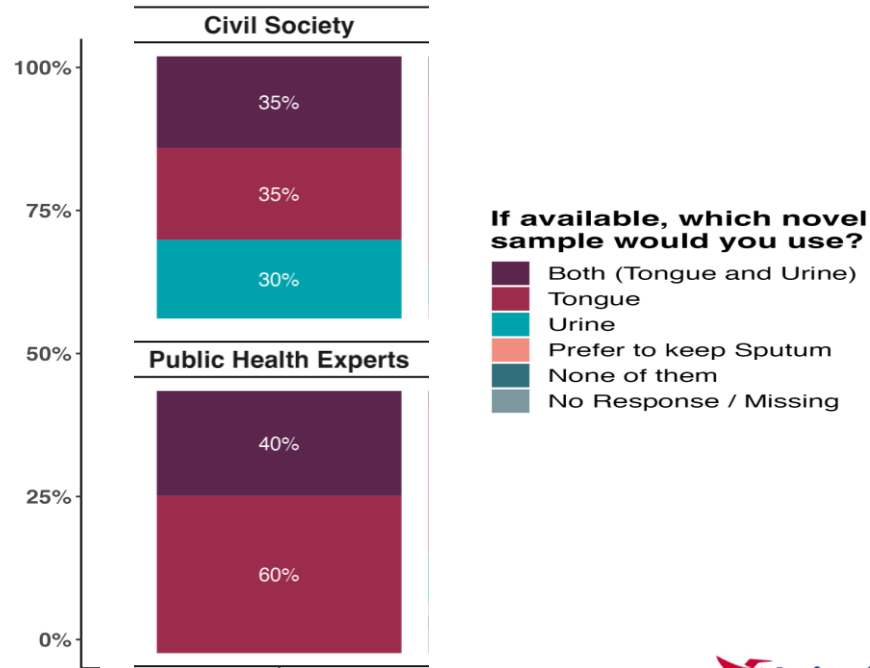
## Health care workers



# Preferences and acceptability of novel sample types



CIVIL SOCIETY AND PUBLIC HEALTH EXPERTS



# Hearing from the end users

## PERCEIVED ADVANTAGES: TONGUE SWAB

- Fast turnaround time for results and treatment initiation
- Relatively cleaner and hygienic sample to collect
- Increase TB testing and TB case finding
- Less stigmatizing and discriminative
- Non-invasive

*“What we want to do is to ensure that more people are tested for TB who might have TB so that we can diagnose them and get them on treatment. Or if they don't have TB and they're high risk, offer them TB preventive therapy. So, it would be a big advantage to increase testing in the country to have a point of care diagnostic to scale up TB diagnosis and get people on treatment if they need it and then also to scale up TB preventive therapy for those who would be eligible.”*



CS, 42, Man, Urban & Rural

## PERCEIVED ADVANTAGES: TONGUE SWAB

- Low Sensitivity and Specificity
- Cost coverage
- Presentation of disease
- Time consuming

*“It's a lot of time, thirty minutes with one patient is a lot of time. The integration will be a problem if this is the amount of time that I will be spending with one patient, remember this is only for the tests, so before this test we would have done the history - that means I am going to spend one hour with one patient. So, it will be a lot [of time].”*



HCW, 48, Woman, Urban

# Hearing from the end users

## PERCEIVED ADVANTAGES – URINE SAMPLE

- Timely diagnosis & treatment initiation
- Easy sample to access

*“..it will assist us to identify the patients early and ensure that those patients are put on treatment as early as possible...it will assist us in achieving this component of early identification and initiation of treatment of TB clients. [The] advantages of point of care urine test will be early identification of TB cases, early start of treatment, reduced rates of lost to follow up and reduced waiting times for results.”*



PH, M, 44, Urban

## PERCEIVED BARRIERS – URINE SAMPLE

- Collection of midstream urine
- General Hygiene
- Time consuming
- Contextual barriers

*“I can say the hygiene part of it, sometimes we don't have water or there is a loadshedding, and then once you ask somebody to go the bathroom, that [person] needs to wash their hands, so when we have loadshedding [and water shortage], it won't work for us.”*



PH, Woman, 38, Urban & Rural

## Key findings | Take away messages

### Difficulties to provide sputum samples

- TB service recipients, HCW, CS, PH experts
- HCWs believe that it is more difficult for TB recipients than they report

### Acceptability of tongue and urine sample types

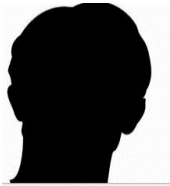
- Higher preference for tongue swab
- Both novel sample types 'Acceptable': There is a need for innovation

### Concerns

- Context: Water shortages & Loadshedding
- Cost coverage to be considered for LMICs

## IN CONCLUSION

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PH, Man, 44, Urban

The one question I'd be asking them [manufacturers] is, what are they waiting for in implementing these [tests]? because honestly these are some of the innovations we want, we want innovations that will enable us to initiate patients [on treatment] early, especially in the context of TB

## Acknowledgements

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