

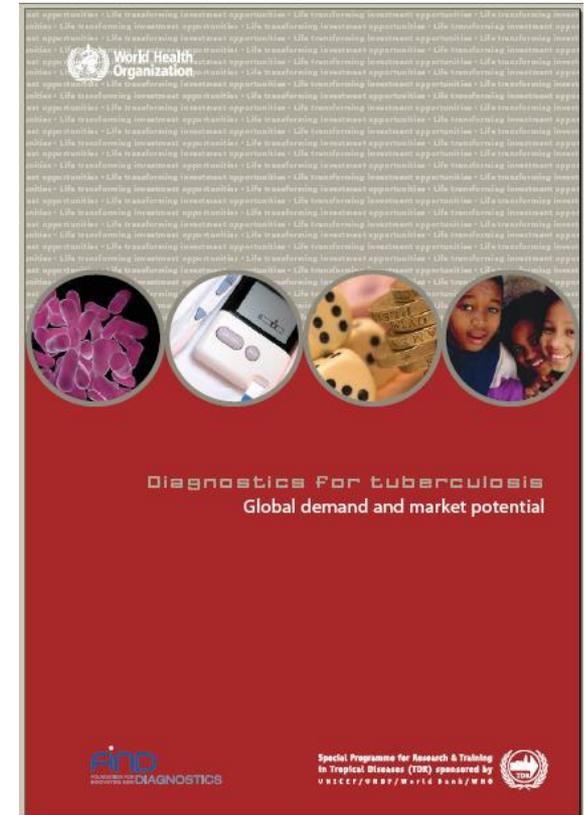
# TB Market Intelligence

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National Priority Programmes  
National Health Laboratory Service  
ASLM, December 2014



# Global TB diagnostic market

- Annually over **US\$ 1 billion** was spent worldwide on TB diagnostics (FIND, 2006)
- One third (US\$ 326 million) was spent outside of the Established Market Economies (EME), where 73% of TB diagnostic testing takes place
- In EME: latent TB testing (PPD) dominates
- In non-EMEs: active TB testing dominates (smears and chest x-rays)





# The need for TB Market Intelligence

- Much has changed in the TB technology landscape in the last decade, thus updated analyses are underway
- New TB diagnostics e.g. Xpert® MTB/RIF assay are being scaled-up, however a great need remains for new TB diagnostic tests
  - In particular for tests that can be used at various levels of the health care system to provide a rapid and actionable result for clinical management during the patient's first clinical encounter
- While the technology pipeline has many new products, there is uncertainty on the current and potential market size for such technologies

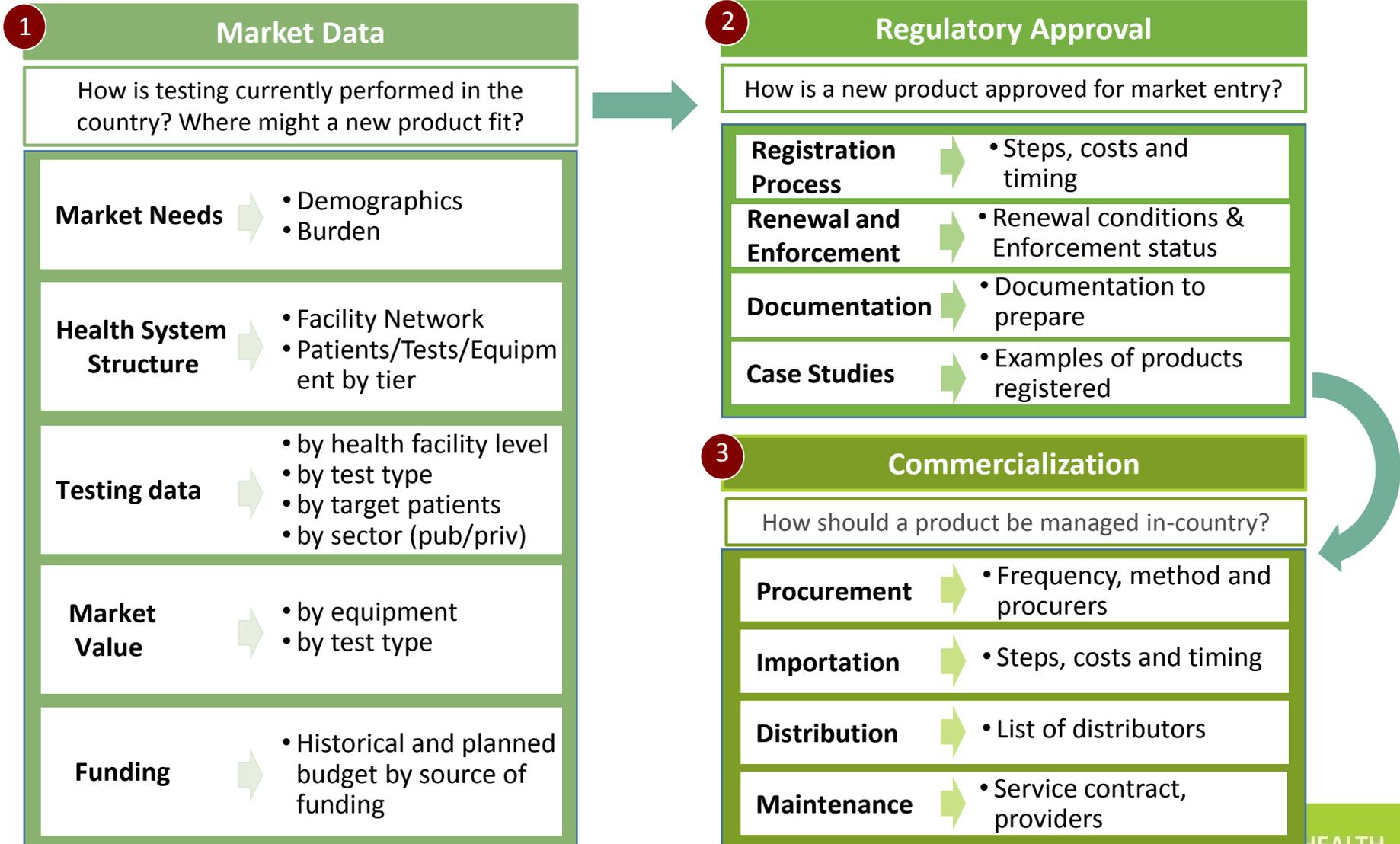


# TB Market Analyses- Clinton Health Access Initiative

- **Goal-** Accelerate market entry of high quality, lower-cost diagnostic products for HIV, TB (& malaria) by supporting developers with product design, market & regulatory intelligence, and enhanced understanding of commercialization opportunities and challenges in low resource markets
- Across 9 countries that represent: *51% of the global TB burden and 35% of the global MDR-TB burden (from sub-Saharan Africa and south Asia)*



# Overview of Data Gathered

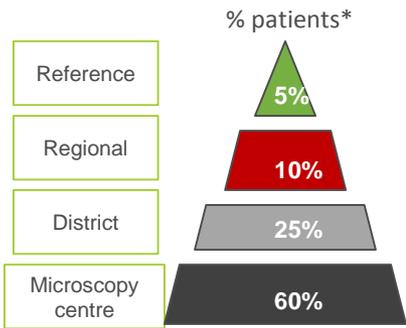


**Sources including:** diagnostic distributors, local suppliers or manufacturers, private laboratory networks, government bodies responsible for regulation, approval, and adoption

# Distribution of Testing

Where are testing volumes occurring in the South African laboratory system?  
How does that differ by test type?

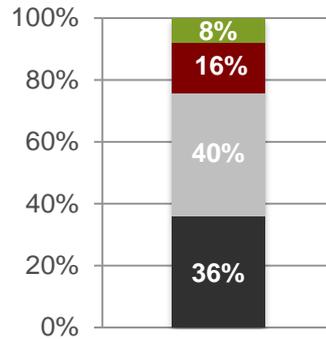
## Laboratory System Structure



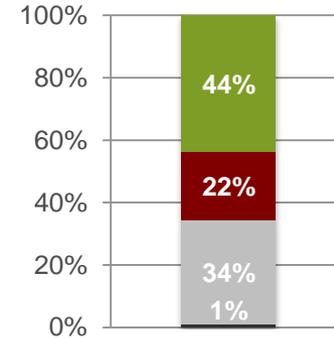
\*Diagnostics for tuberculosis: Global demand and market potential, FIND, WHO, 2006

## SOUTH AFRICA

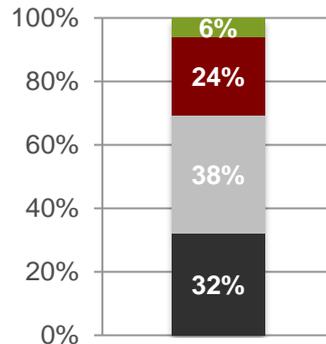
SMEAR MICROSCOPY



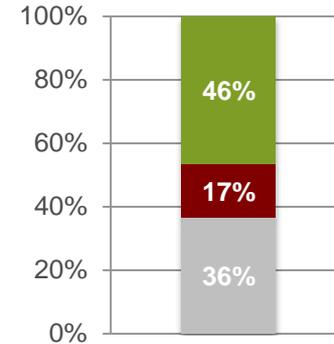
CULTURE\*\*



GENEXPERT



DST\*\*\*



\*\* Culture refers to MTB testing only

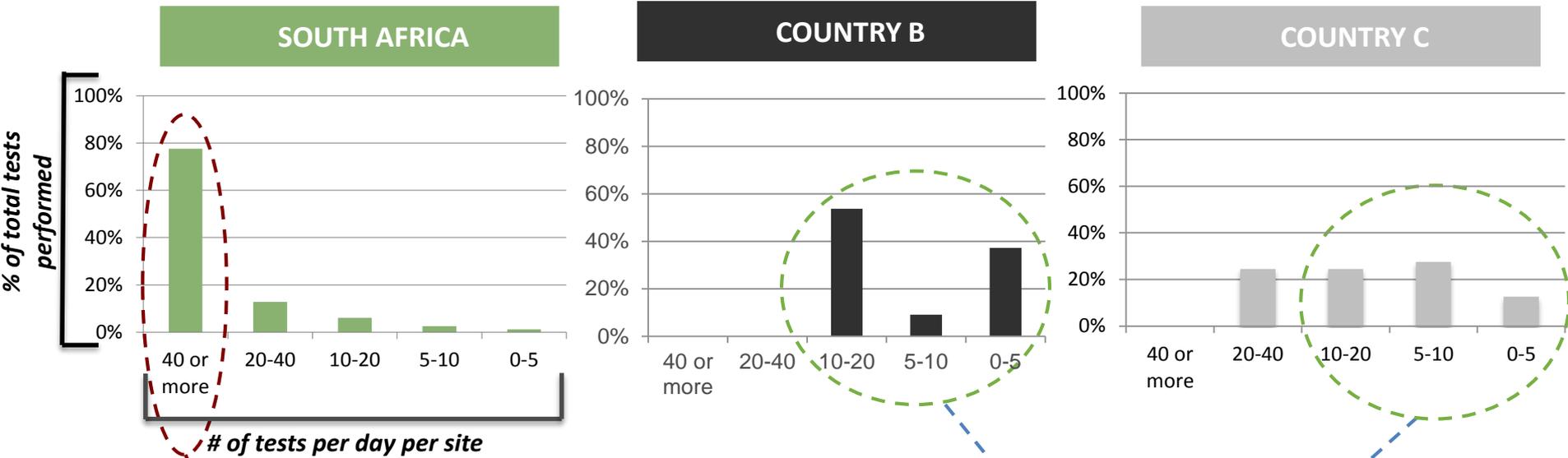
\*\*\* DST includes all testing platforms: liquid and solid culture and line probe assay

# Product-Specific Usage

How are instruments being used in-country?

What throughput should a competitor target in order to replace existing testing platforms?

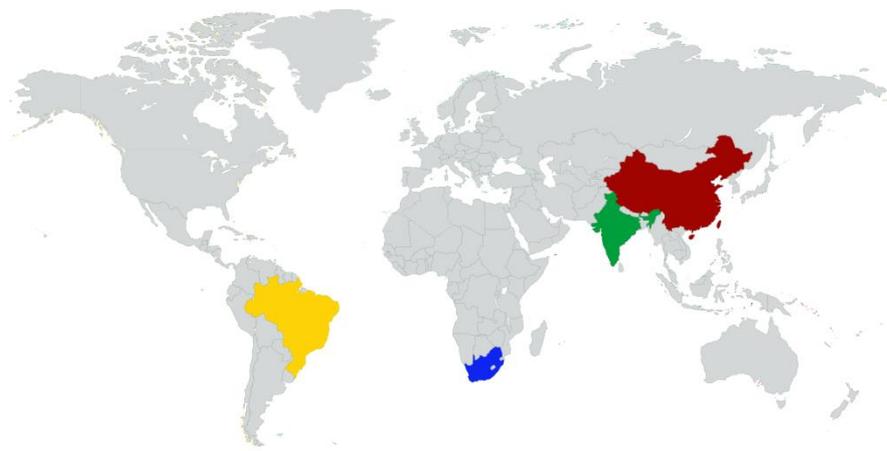
For example, for every site that has a GeneXpert, how many tests is it running per day?



South Africa sees **nearly 80% of its GeneXpert tests** performed at labs that are running **40 or more tests per day**.

**100% of testing volumes in Country B and 75% of testing volumes in Country C** occur at sites that do **20 tests or less per day**

# TB Market Analysis- TB Diagnostic Market Analysis Consortium



Individual country analysis of the current served available market (SAM) of TB diagnostics in 2012/2013:

- South Africa
- Brazil
- China
- India

Collaborators:



McGill

Centre  
international  
de TB McGill



McGill  
International  
TB Centre

+ in-country partners!!

Project funded through a grant from:

BILL & MELINDA  
GATES *foundation*

LTH  
/ICE

National Priority Programmes



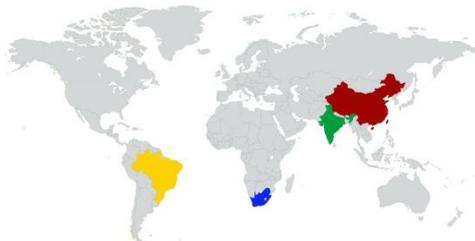
# Determining the current SAM in 4 focus countries

- **Scope:**

- Rapid assessment of the served available market (SAM) for TB diagnostics in Brazil, India, China, and South Africa in **2012/13**.

- **Tests included:**

- Tests done for the diagnosis of **LTBI, active TB** or **treatment monitoring**, and **DST**
- Tests done in the public as well as non-public sector (private / hospital sector)





# Determining the current SAM in 4 focus countries

- **Approach:**

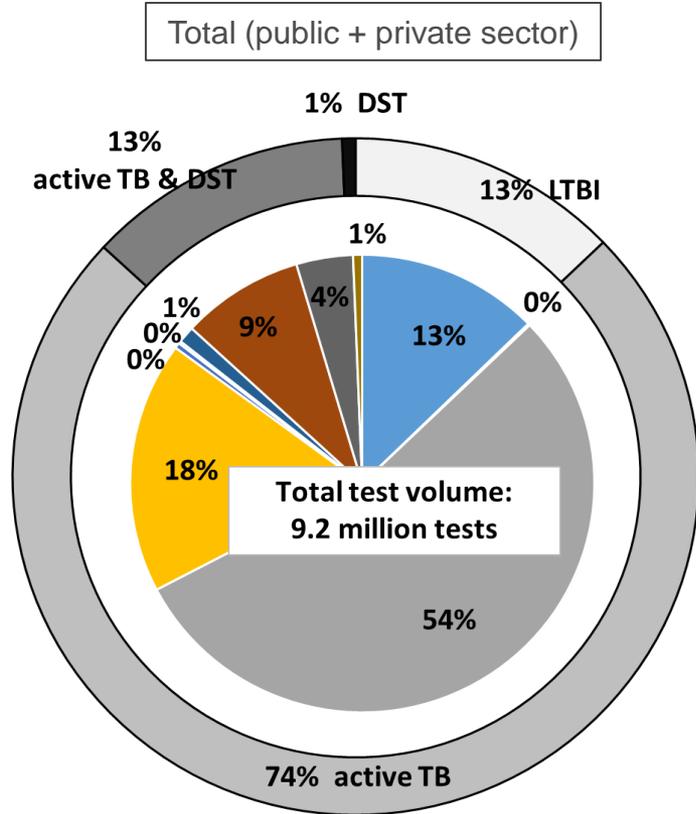
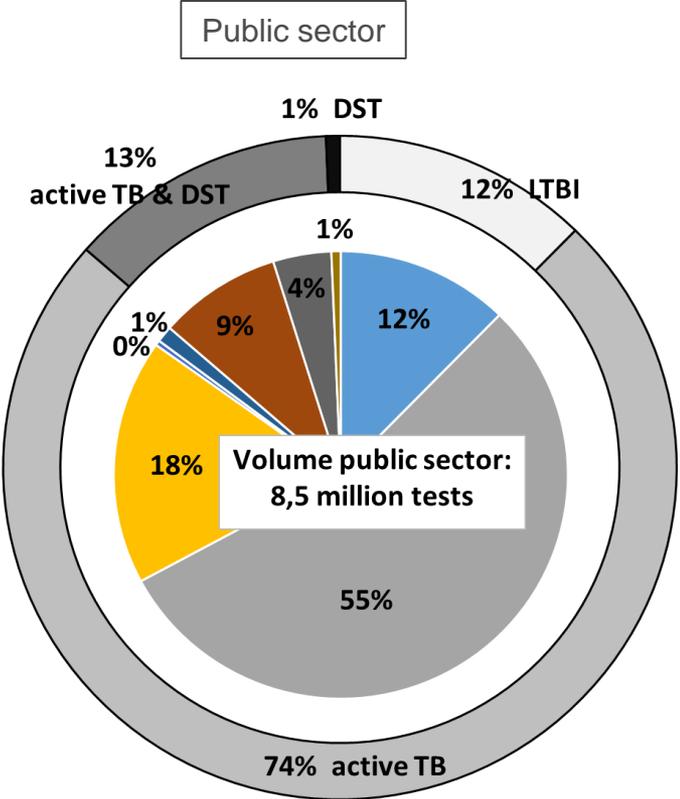
- Bottom-up (collection of tests volumes done and cost of tests) for the public sector.
- Top-down approach (sales information from manufacturers) to estimate the size of the private sector.

- **Output:** market size (#) and market value (\$):

- **Public sector:** test volumes public sector \* cost per test public sector
- Private (non-public sector): test volumes private sector \* prices charged per test
- **Total (both sectors combined):** total test volumes \* **cost per test public sector**

# South Africa: TB diagnostic market size (2012)

<b>TB incidence (/100.000)</b>	<b>1003</b>
# of TB patients notified (2012)	349,582

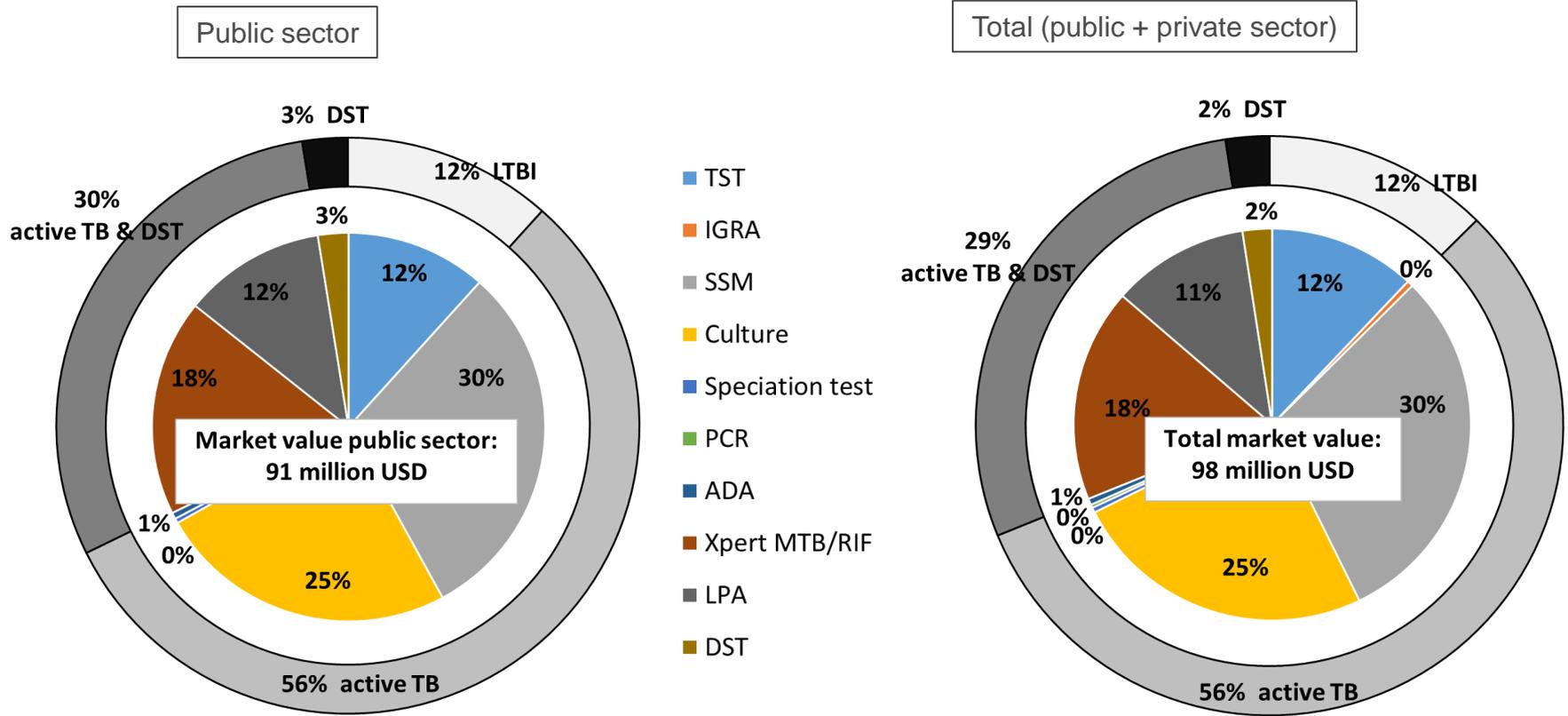


- TST
- IGRA
- SSM
- Culture
- Speciation test
- PCR
- ADA
- Xpert MTB/RIF
- LPA
- DST

- Public sector: 93% of test volumes, Private sector: 7%.
- Vast majority of test volumes are smears and cultures



# South Africa: TB diagnostic market value (2012)



- Relatively more costs are spent on tests that diagnose active TB and DST (Xpert & LPA).
- Testing practices in public and private sector much alike
- Considerable market value and broad range of tests in use

# South Africa: TB diagnostic market changes (2012 vs 2013)

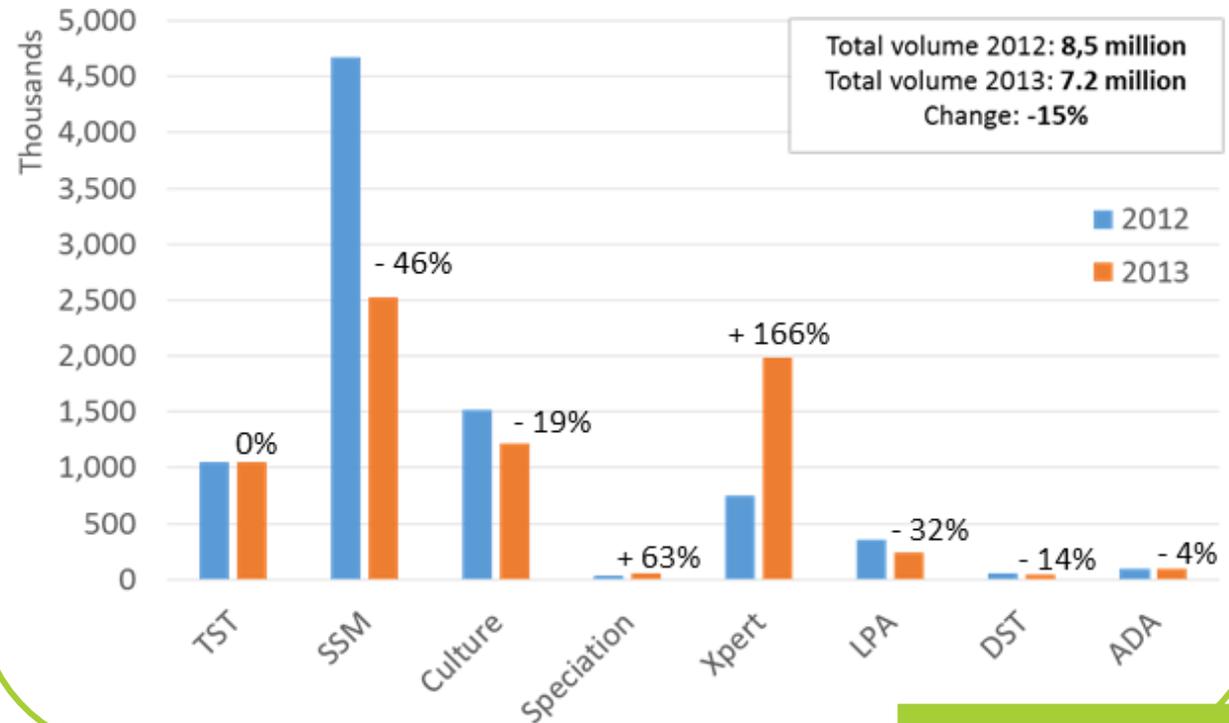
## Xpert scale up:

- ongoing in 2012.
- completed in Sept 2013.

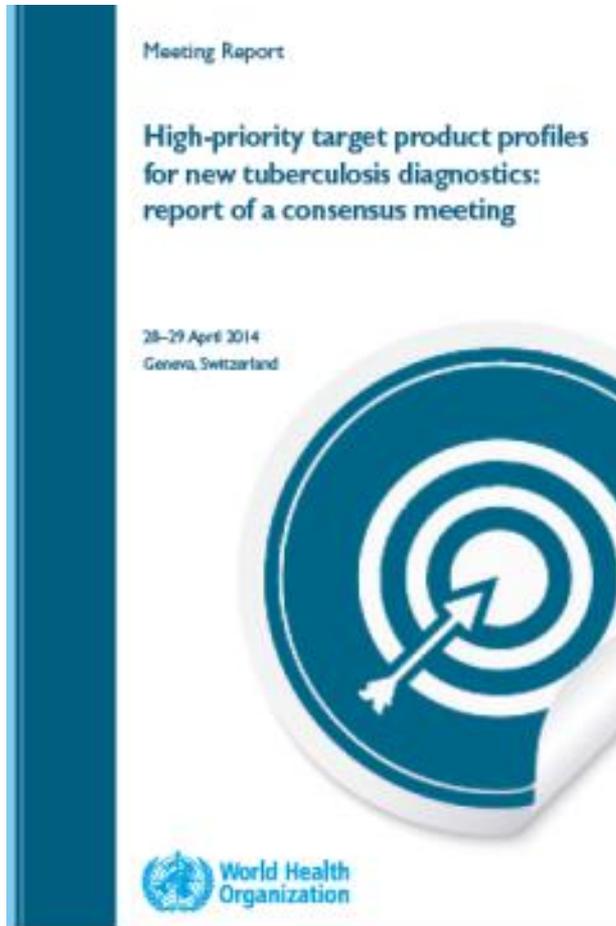
## Resulted changes:

- Decrease in SSM, culture and LPA volumes
- Increase in Xpert test volumes.
- Increase in market value to USD 101 million (10% increase)

Changes in public sector TB test volumes in South Africa



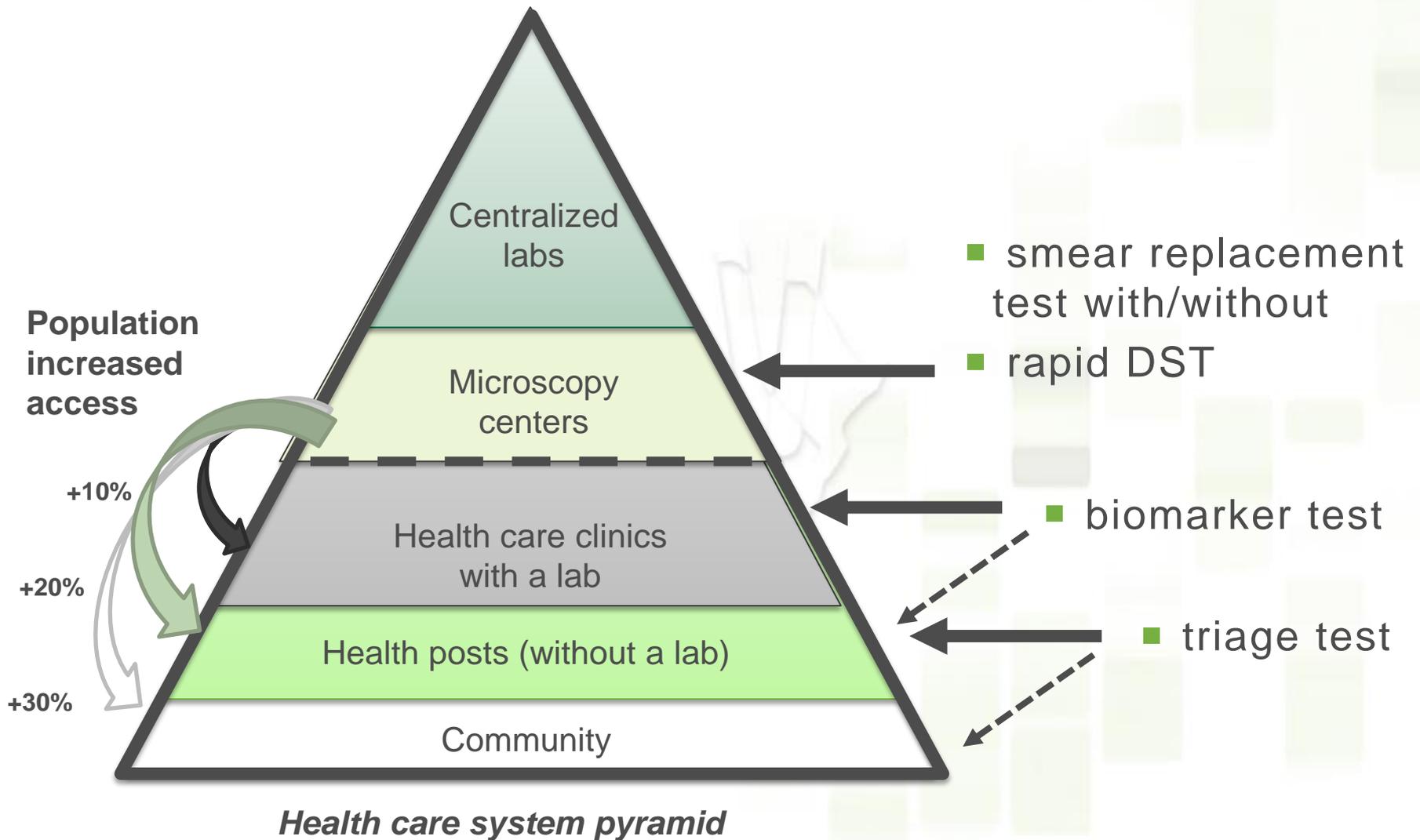
# Potential Market for high priority Target Product Profiles (in progress)



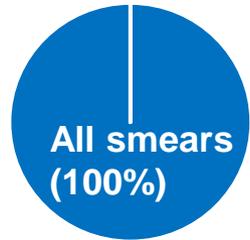
Target Product Profile	Priority Review	Assessment
TPP for a sputum-based TB detection test for identification of TB suspects	High	High
TPP for a rapid, biomarker-based TB detection test for non-sputum samples	High	High
Target Product Profile: Rapid sputum-based molecular test (for microscopy centers) for TB	High	High
Target Product Profile: DST Next Generation	High	High

- **TPP1: biomarker test (non-sputum based)**
- **TPP2: triage test**
- **TPP3: sputum-based smear replacement test**
- **TPP4: sputum-based test with rapid DST (either in one single test or as two separate reactions)**

# WHERE ARE NEW TESTS FORESEEN TO BE PLACED?



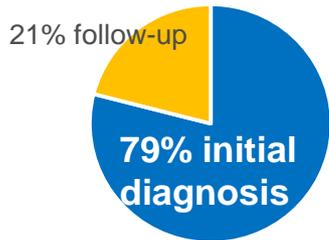
# Potential smear replacement market in 22 HBC (public sector only)



## Current smear diagnostic market (All smears; initial + follow-up)

77.6 million smears \* Average of 1.77 USD = **\$137 million** (range \$100-\$209 million USD)\*

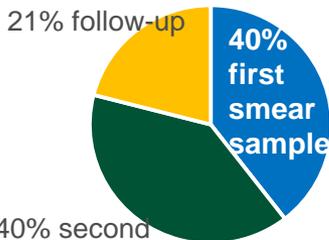
Public sector only!



## Current smear diagnostic market (diagnostic smears only)

79% \* 77.6 million = 61.3 million smears done for initial diagnosis

2 diagnostic smears per person



## Potential smear replacement market (one diagnostic sample only)

30.7 million \* 5 USD (assumed test cost for replacement test) = **\$153 million**

40% second smear sample





## Conclusions

- Market analysis of TB diagnostics demonstrated that South Africa has a substantial TB diagnostics market both in terms of volume and value that includes a broad range of tests
- Since the analysis covered the period of roll-out of Xpert, it provides insights into how markets change in volume and value with the introduction of new tools
- Potential market for high priority TPPs could be considerable going forward

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