



Business case of investing in TB diagnostics in India

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Important note

This is a draft/preliminary analysis of the TB diagnostics market in India. Further work is necessary to complete the analysis, based on feedback received during the conference.

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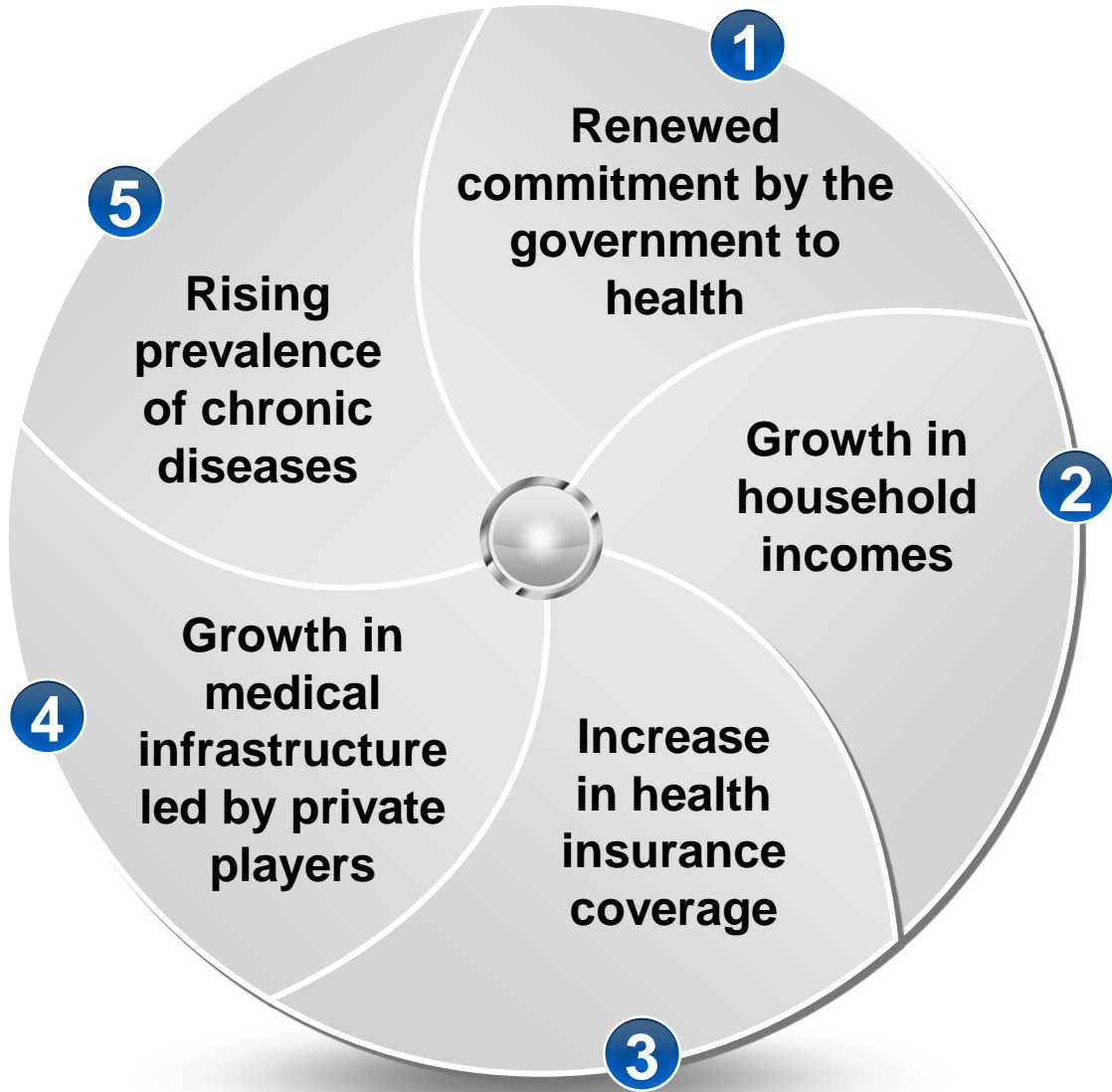
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4 New TB diagnostic tests – commercial opportunity



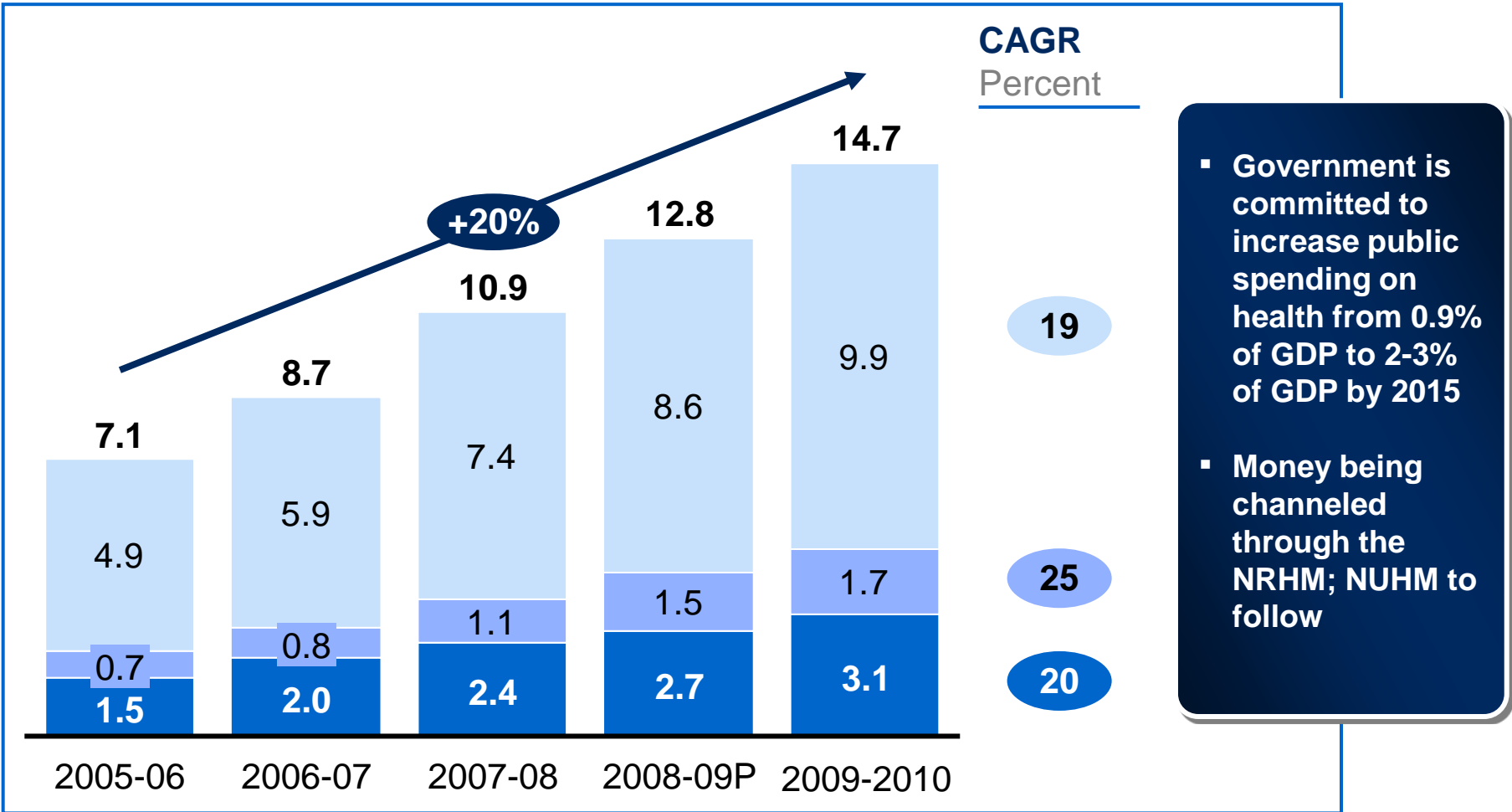
5 factors will drive the pace of the health-care market evolution in India



1 Government of India has made a commitment to increase spending on health

Annual government health spending¹
USD Billion

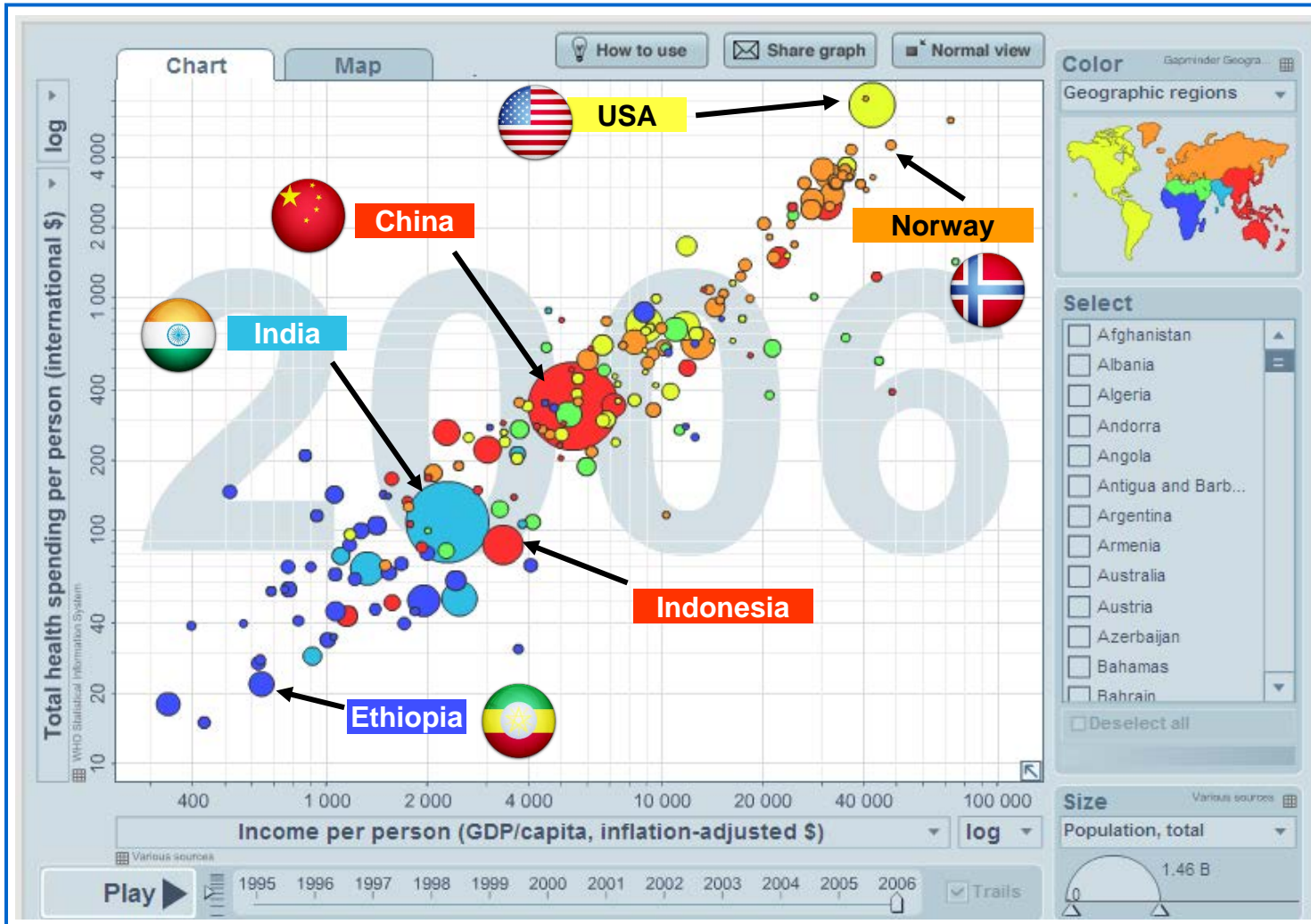
- State health spend
- Central non-NRHM health spend
- NRHM³ spend (central)



- Government is committed to increase public spending on health from 0.9% of GDP to 2-3% of GDP by 2015
- Money being channeled through the NRHM; NUHM to follow

2 There is a strong correlation between GDP per capita and healthcare expenditure per capita

Health-care expenditure and GDP per capita (2006)



India is expected to move along the curve as its GDP continues to grow

3 Health insurance penetration is increasing rapidly – driven by RSBY scheme for BPL population

Components	Key drivers	Coverage Million	
		2006	2015
Traditional premium-based health insurance	<ul style="list-style-type: none"> Removal of regulatory hurdles Active market shaping by players Entry of new competitors Increasing consumer awareness 	25-30	~125
Social insurance/welfare funds	<ul style="list-style-type: none"> Relaxation in income ceiling or enterprise criteria 	35-40	~50
Employer provided (sponsored benefits)	<ul style="list-style-type: none"> Employers shifting to premium-based coverage plans Low growth in public sector employment 	30-35	~35
Community insurance (self-funded)	<ul style="list-style-type: none"> Increased efforts of NGO/self-help groups 	2-3	8-10
Rashtriya Swasthya Bima Yojana (RSBY)	<ul style="list-style-type: none"> Provide protection to BPL households from financial liabilities arising out of health shocks 	96-99	~300
		188-217	~520

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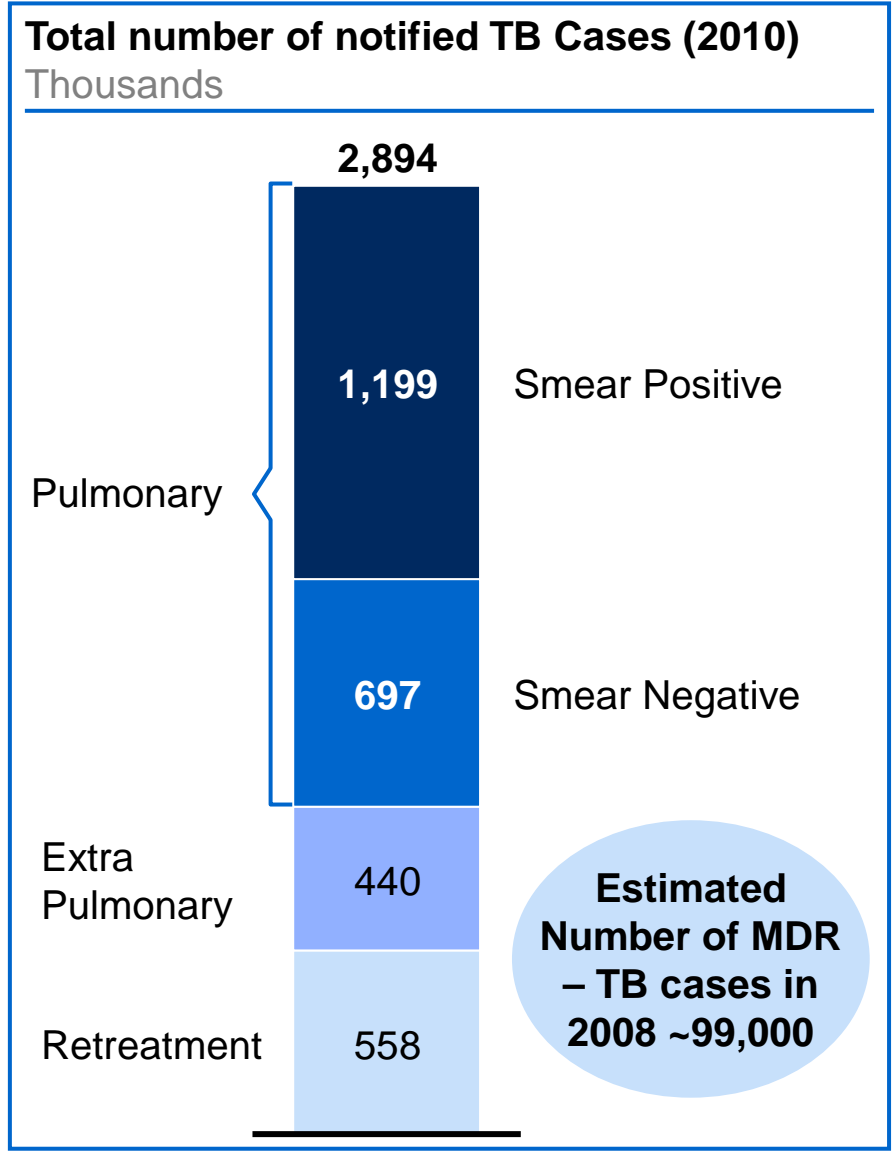
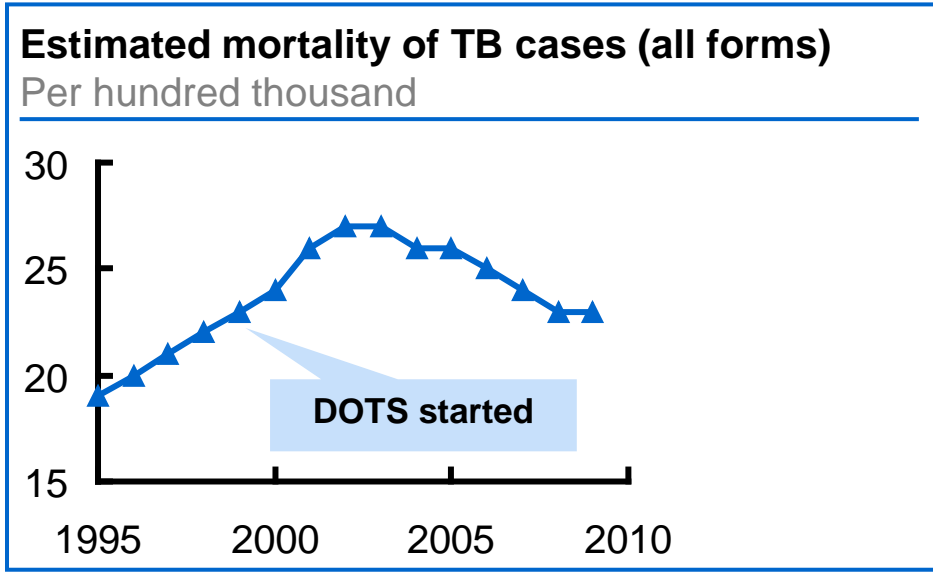
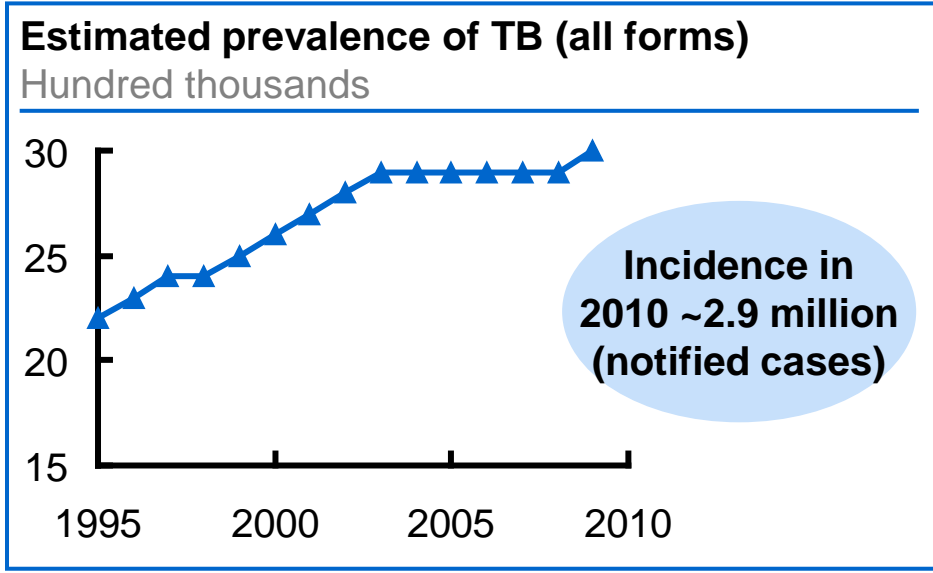
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TB Burden in India is high, though mortality trends have improved



TB Diagnostics in India (1/2)

	Description	Evaluation
Sputum Smear Microscopy	<ul style="list-style-type: none"> This diagnostic method involves microscopic examination of stained sputum smeared on a glass slide If the bacteria is present in sufficiently high concentrations, it can be readily identified Sample: Sputum 	<ul style="list-style-type: none"> Sensitivity <ul style="list-style-type: none"> High infection: 86% Low infection: 35-70% (especially in case of HIV patients, children and extra pulmonary TB) Specificity: 97% Duration: 2 hours Number of Visits: 2-3
Cultures	<ul style="list-style-type: none"> In this process, bacilli from the sputum is cultured for a few weeks to detect TB. It requires only 10-100 bacilli per ml as compared to 5,000/ml of sputum required in smear microscopy It takes a longer time than smear and is more expensive to perform Sample: Sputum 	<ul style="list-style-type: none"> Sensitivity <ul style="list-style-type: none"> High Infection: 100% Low Infection: 73% Specificity: 99% Duration: 2-6 weeks Number of Visits: 2-3
Serological Antibody tests (Rapid/ELISA)	<ul style="list-style-type: none"> Involves identification of antibodies which are formed in response to the bacteria with the help of an enzyme linked detection antibody and antigen This process has lower specificity as the antibodies react with environmental mycobacteria leading to false positives Sample: Blood 	<ul style="list-style-type: none"> Sensitivity (high only in case of smear positive) <ul style="list-style-type: none"> High infection: 76% Low infection: 59% Specificity: 87% Duration: 15 minutes - 1 hour Number of Visits: 1-2

TB Diagnostics in India (2/2)

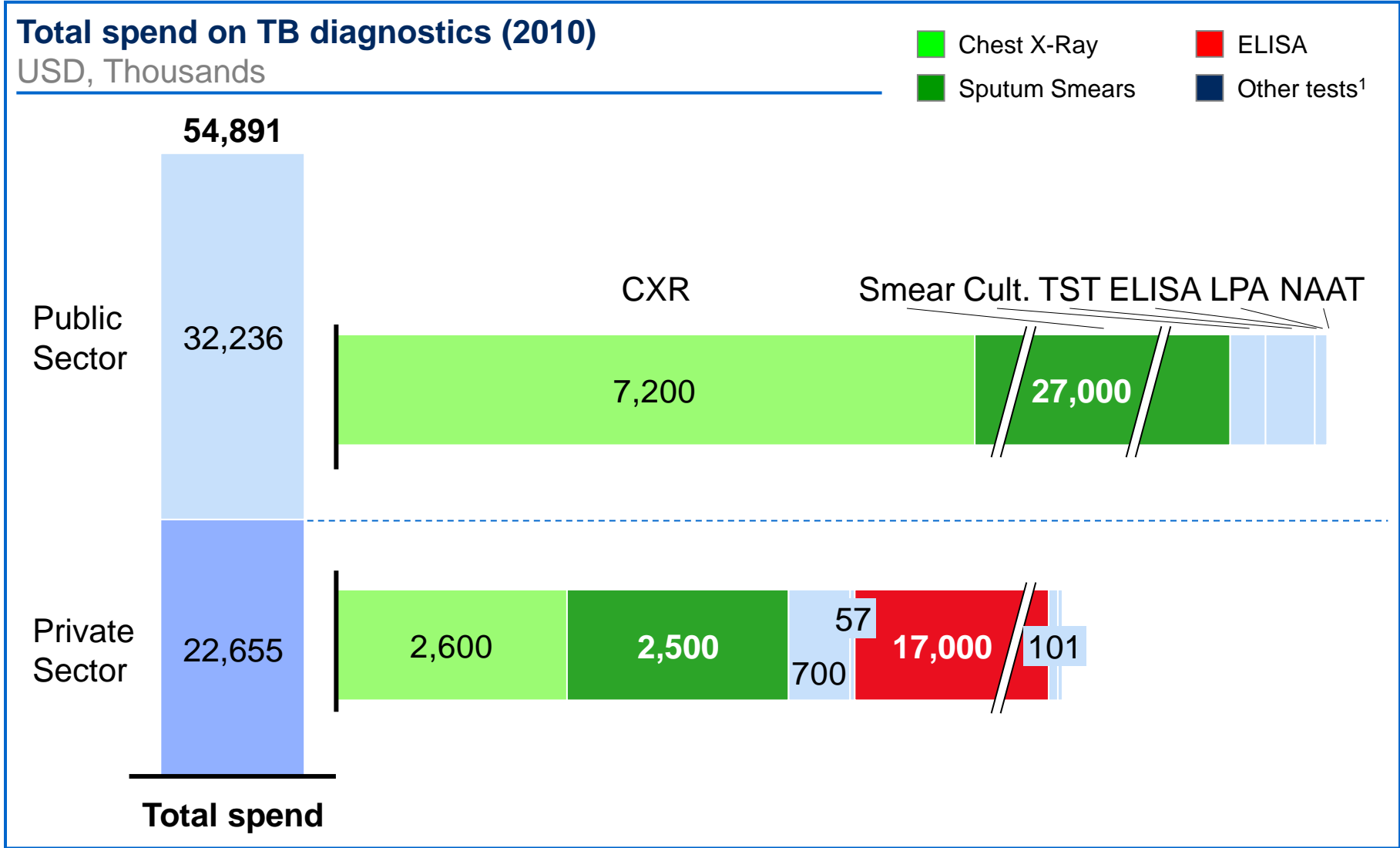
	Description	Evaluation
Chest x-rays	<ul style="list-style-type: none"> ▪ Radiographic method for detection of tuberculosis ▪ However many studies have shown that no radiographic pattern is diagnostic of tuberculosis as many lung diseases have similar radiographic pattern that can easily mimic tuberculosis 	<ul style="list-style-type: none"> ▪ Sensitivity : High except in cases of patients infected by HIV ▪ Specificity: Non Specific ▪ Duration: 1 hour ▪ Number of Visits: 1
Tuberculin skin test (TST)	<ul style="list-style-type: none"> ▪ Involves injection of Tuberculin or Purified Protein Derivative (PPD) under the forearm skin ▪ In patients with prior TB infection it causes hypersensitivity and leads to skin thickening at injection site ▪ IGRA tests can be used following a positive TST to support diagnosis of latent TB or as an alternative to TST for screening health care workers 	<ul style="list-style-type: none"> ▪ Sensitivity: varies depending on the population tested ▪ Specificity: varies depending on the population tested ▪ Duration: 48 hours ▪ Number of visits: 1
Nucleic Acid Amplification Test (RT PCR)	<ul style="list-style-type: none"> ▪ Involves enzymatic amplification of bacterial DNA, which is detected with an appropriate reading system via a signal generating probe ▪ Sample: Sputum, Blood, Urine 	<ul style="list-style-type: none"> ▪ Sensitivity <ul style="list-style-type: none"> – When smear positive: 95% – When smear negative: 60-70% ▪ Specificity: 98-100% ▪ Duration: 2.5-3.5 hours ▪ Number of visits: 1

Estimated volumes of TB diagnostics done in India

	Public sector	Private sector
Sputum Smears	<ul style="list-style-type: none"> ~7.5 million sputum microscopy tests conducted every year through RNTCP 	<ul style="list-style-type: none"> Approximately 700,000 to 1,100,000 sputum smears are conducted every year
Cultures and LPA	<ul style="list-style-type: none"> ~10,000 tests (including liquid, solid cultures and LPA) conducted for MDR-TB cases (also includes DST) 	<ul style="list-style-type: none"> Very few culture tests are conducted as the time taken to obtain results is very long ~ 8,000 to 18,000 tests
Serological (Rapid/ELISA)	<ul style="list-style-type: none"> Public Sector in India does not use the serological tests 	<ul style="list-style-type: none"> More than 1.5 million tests every year
Chest X- Rays	<ul style="list-style-type: none"> Public Sector conducts about ~2.3-3.2 million Chest X-Rays every year 	<ul style="list-style-type: none"> Approximately 450,000-670,000 Chest X-Rays are conducted every year for TB diagnosis
Tuberculin skin test	<ul style="list-style-type: none"> Approximate 300 vials are used every year for 1 million people. Leading to ~360,000 tests every year 	<ul style="list-style-type: none"> ~20,000 to 35,000 TST's are conducted every year in the private sector
NAAT (RT PCR)	<ul style="list-style-type: none"> PCR tests not conducted under RNTCP for active TB 	<ul style="list-style-type: none"> Very few PCR's are conducted since they are very expensive tests and require high level infrastructure ~1,000 to 1,500 tests

TB Diagnostics – Spend analysis

PRELIMINARY



¹ Other Tests include Solid & Liquid Cultures, Tuberculin Skin Test, LPA and RT PCR

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The world needs a new TB diagnostic test

High TB Burden

- In spite of many TB Diagnostics available in the market, TB remains world's largest treatable infectious cause of death, killing 5000 people everyday

Poor access to fair diagnostics

- 60 % people seeking health care go to either the health post level or peripheral health clinics, where adequate laboratory infrastructure to perform TB investigations often do not exist
- Many people living in the rural areas also do not have access to fair diagnostics

Sputum as a specimen

- All routine lab based TB tests available to date depend on respiratory specimens which are highly susceptible to significant quality variability
- Two most vulnerable populations to TB infection, children and people infected with HIV are either unable to produce sputum or produce paucibacillary specimen respectively

Sensitivity and specificity

- Diagnostic methods such as smear microscopy has low sensitivity especially in cases of children, people infected with HIV and extra pulmonary TB
- Tests such as ELISA have very low sensitivity and specificity as they are antibody based which can be produced in response to other organisms as well

Time to Results

- Diagnostic tests like bacterial culture have high sensitivity and specificity as compared to smear microscopy but the time to results is so long that the disease gets transmitted to other people till it is diagnosed

High infrastructure, training needs

- Tests such as PCR are highly sensitive and specific but their implementation requires high level infrastructure laboratories which are very expensive and cant be made available in rural areas
- These tests also require proper training of the staff which makes the test even more expensive

Current understanding of an ideal TB diagnostic

Test specification	Minimum required value
Sensitivity	<ul style="list-style-type: none"> ▪ 95% for smear positive, culture positive patients ▪ 60-80% for smear negative, culture positive patients
Specificity	<ul style="list-style-type: none"> ▪ 95% compared to culture (for both adults and children) ▪ 90% for culture negative probable TB (in children)
Training and controls	<ul style="list-style-type: none"> ▪ Be easy to use for nurse or community health worker (even with minimal training) ▪ Positive control in Test Kit
Time to results and readout	<ul style="list-style-type: none"> ▪ 3 hours maximum, patients must receive the results the same day, desirable would be 15 minutes ▪ Should be readable for 1 hour, should be a simple readout 'yes' or 'no'
Specimen type	<ul style="list-style-type: none"> ▪ Adults: Urine, oral, breath, venous blood ▪ Children: Urine, oral, capillary blood (finger/heel prick)
Cost to patients	<ul style="list-style-type: none"> ▪ Less than USD 10 per test after scale up
Throughput and Power Requirement	<ul style="list-style-type: none"> ▪ Throughput: 20 tests/ staff member / day ▪ Power Requirement: Should be able to run on battery
Sample preparation	<ul style="list-style-type: none"> ▪ Maximum three steps should be involved ▪ No need for pipetting and no time sensitive process should be involved
Instrumentation	<ul style="list-style-type: none"> ▪ No maintenance costs, acceptable replacement costs ▪ Works in tropical conditions, fits in backpack and is shock resistant
Storage and waste disposal	<ul style="list-style-type: none"> ▪ Shelf life 24 months including reagents, stable in high humidity and high temperatures ▪ Disposal: simple burning or sharps, no glass

Key features needed for new TB diagnostic tests in the Indian context

Critical factors for new test in India

- Sensitivity >90%
- Specificity >90%
- Time to result ~ up to 24 hours¹
- Specimen type – may be urine or blood – NOT sputum
- Sample preparation – less than 3 steps
- Instrumentation – should work in tropical environment; fit in a back pack; dust and shock resistant
- Power requirements – should be able to work on car battery back up
- Cost – to patient should be ~ Rs 600/- per test

Potential approaches to get there

- Pathobiology
 - Pathogen based approaches
 - Attack known biomarkers (e.g., rpoB gene)
 - Nuclei acids based tests
 - Host responses
- Instrumentation engineering
- Disruptive approaches e.g.,
 - Optical
 - Electronics
 - Materials technologies etc.

¹ As most people in India now have mobile phones, test results could be reported over phone and patients no longer need to wait in the lab for results

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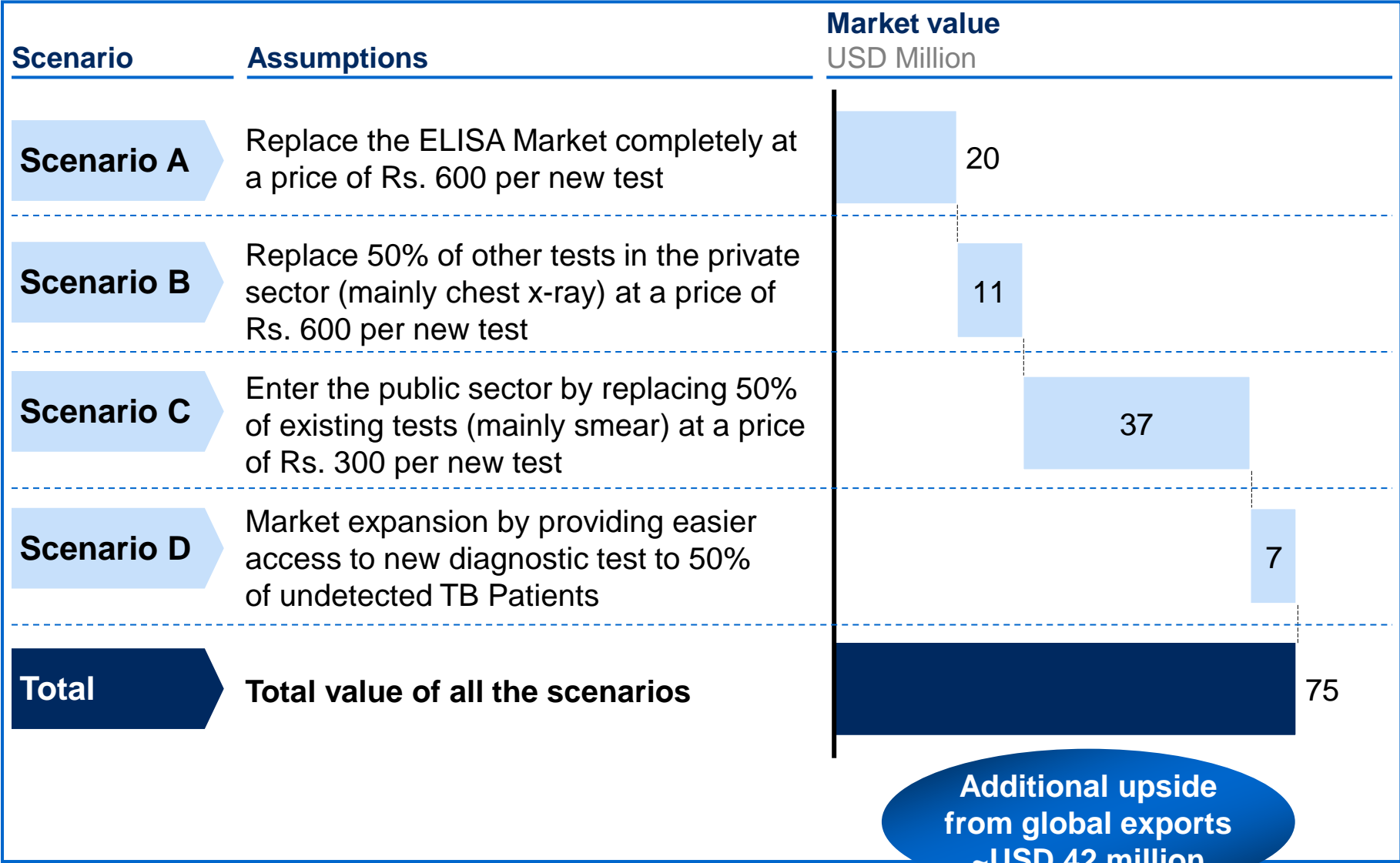
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Market potential for the new TB diagnostic



Commercial approaches for capturing this opportunity



Key capabilities needed

Go your own way

- Need to develop a go-to-market capability including sales, distribution, collections, after sales service etc.

Partnership with existing players

- Need to identify the right commercial partner (e.g., a Pharma/device company with the sales and distribution capabilities), develop the partnership and scale up commercially

Government focus

- Become familiar with government procurement processes and participate in tenders and other contracts