

December 2010: Geneva Consultation GXP



NATIONAL HEALTH
LABORATORY SERVICE

NTBRL

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2 December 2010

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Wat maak dood?

74 863

mense sterf aan TB. Ander vigsverwante siektes soos longontsteking en maagaandoenings is die tweede en derde grootste oorsake van natuurlike sterftes.

5 785

mense sterf in padongelukke

5 467

mense sterf weens aanranding

734

sterftes was weens komplikasies ná mediese of chirurgiese behandeling

91,3%

van alle sterftes was weens natuurlike oorsake soos siektes. Die res is onnatuurlik, waaronder moord en ongelukke.

Die oorsake van

40 000

onnatuurlike sterftes blyk nie duidelik uit die doodsertifikate nie.



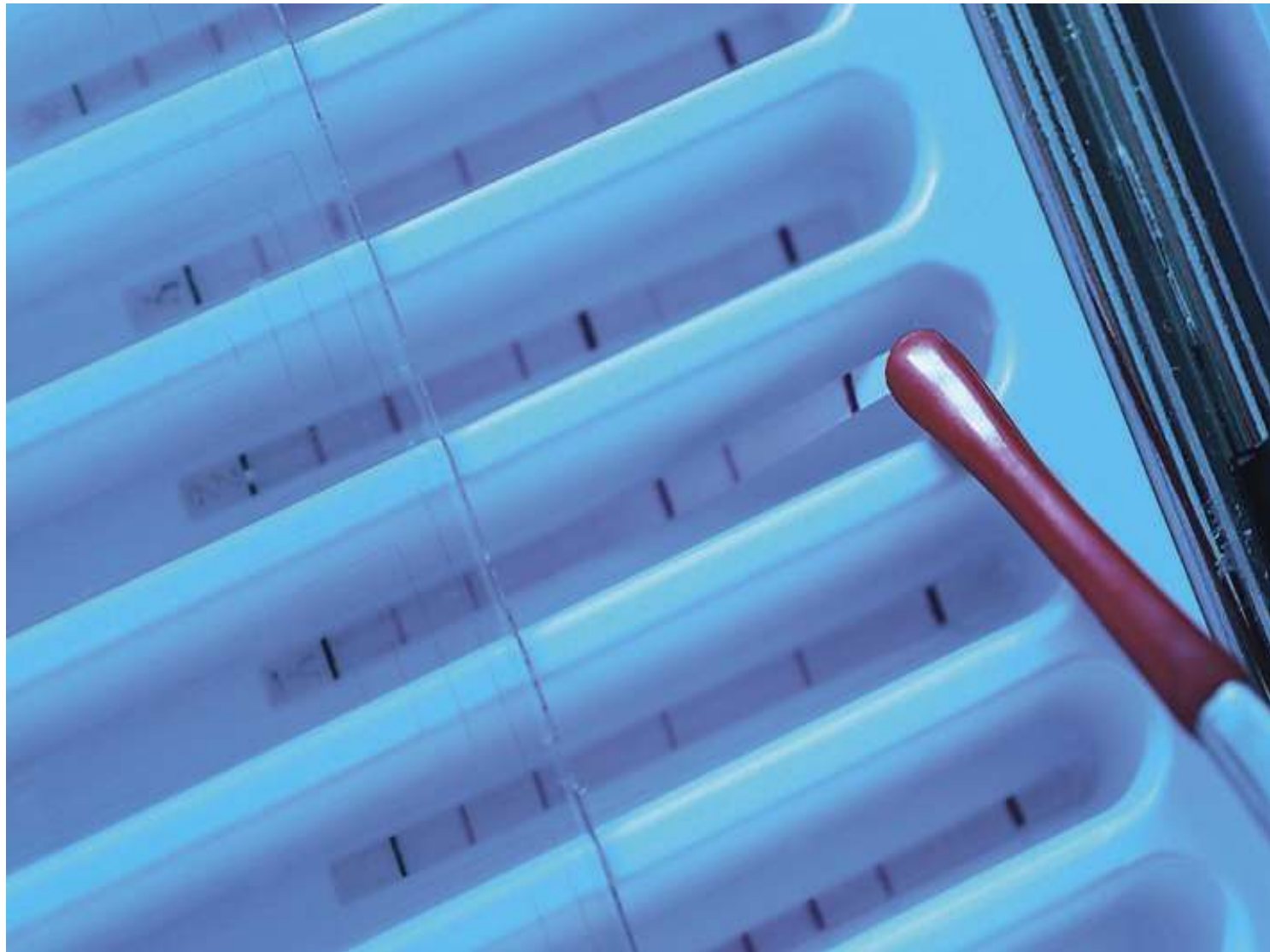
Check
FOR
QUALITY



DNA•STRIP® TECHNOLOGY



NATIONAL HEALTH
LABORATORY SERVICE





VOLUMES PER ANNUM

Year	CULTURE	MICROSCOPY	DST LPA	DST MGIT
2004	273,829	1,815,333		34,542
2005	349,246	2,300,241		36,871
2006	481,757	2,720,813		48,049
2007	581,671	2,927,017	5,963	64,943
2008	729,424	3,373,134	23,126	58,887
2009	759,643	3,276,347	61,423	39,334
2010 (Proj)	844,212	4,449,532	90,266	31,408
2010 (Q1&2)	422,106	2,224,766	45,133	15,704



Table 3: Number of MDR-TB patients diagnosed by the NHLS by province per year

PROVINCE	2004	2005	2006	2007	2008	2009	Grand Total
EASTERN CAPE	379	545	836	1,092	1,501	1,858	6,211
FREE STATE	116	151	198	179	381	253	1,278
GAUTENG	537	676	732	986	1028	1,307	5,266
KWAZULU-NATAL	583	1,024	2,200	2,208	1,573	1,773	9,361
LIMPOPO	59	40	77	91	185	204	656
MPUMALANGA	162	134	139	506	657	446	2,044
NORTH WEST	130	203	225	397	363	520	1,838
NORTHERN CAPE	168	155	188	199	290	631	1,641
WESTERN CAPE	1,085	1,192	1,179	1,771	2,220	2,078	9,525
Grand Total	3,219	4,120	5,774	7,429	8,198	9,070	37,810

Only 104
patients
registered at
MDR centre

GeneExpert Platforms

GeneExpert[®]
Module



GX-1



GX-4



GX-16



GeneExpert
Infinity-48





- ✘ Xpert MTB-RIF rather than conventional microscopy, culture and DST should be used to test individuals suspected of having MDR-TB or HIV associated TB
 - + Strong recommendation; high (moderate) quality evidence
 - + Remark: This recommendation also applies to children

- ✘ GXP may be considered as a follow-on test to microscopy in settings where MDR-TB or HIV is of lesser concern
 - + Conditional recommendation acknowledging major resource implications; high (moderate) quality evidence.





- × Consensus on the following:
 - + Do we implement GXP for NTP use in SA
 - + Where in the existing NTP diagnostic algorithm
 - × Add-on vs replacement test
 - + Is GXP affordable in SA
 - + How are we going to interpret results
 - + Clinical guidelines
 - + Do we wait for the next generation tests
 - + Do we need to pilot GXP to evaluate positioning





Sites (provisional)

Klerkdrorp/Thepong (with 4 satelites)

Welkom

Tugela Ferry

Polokwane

Bombela (satelite)

TAH

Umtata

Upington

Khayelitsha

Malmesbury ID

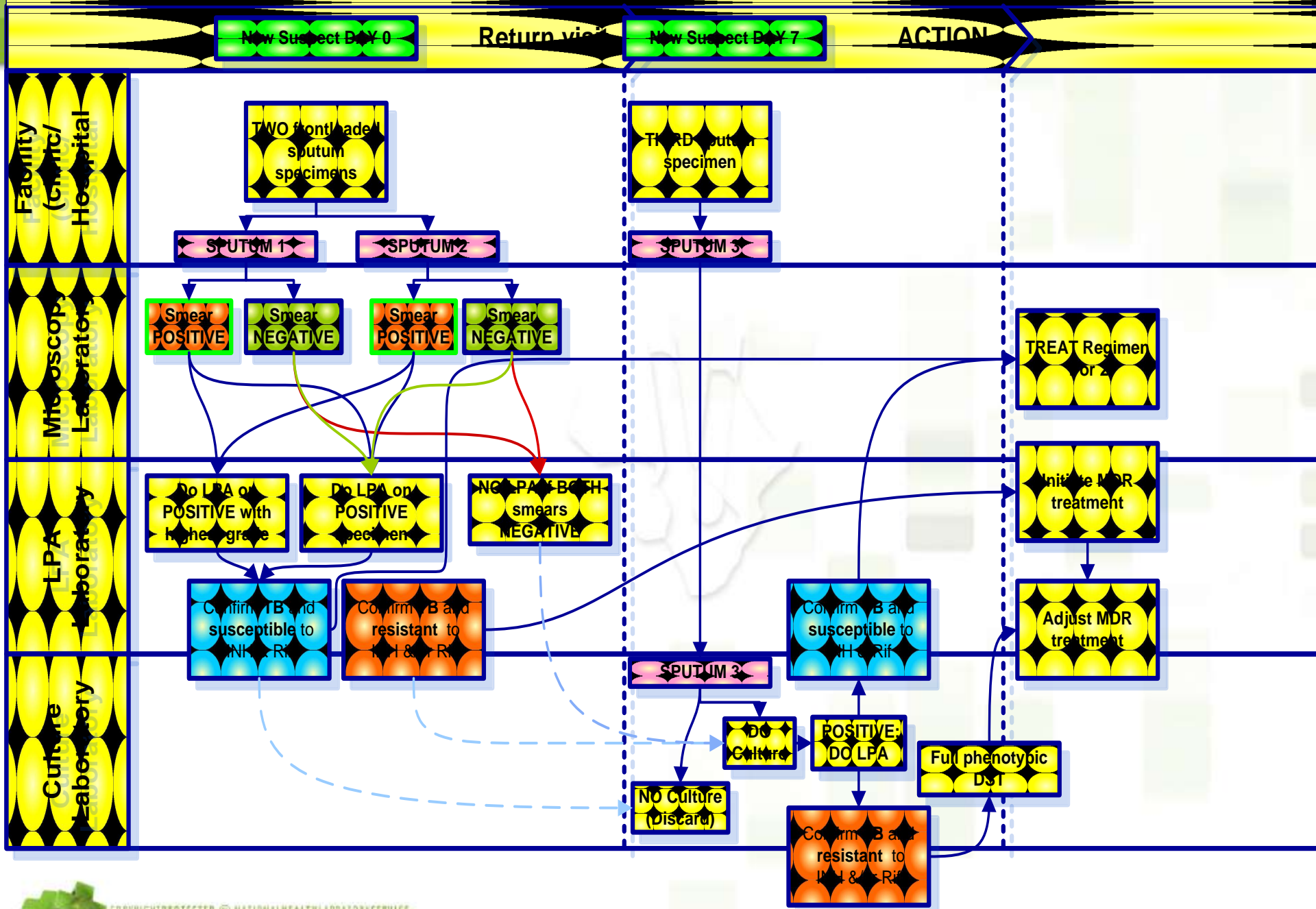




- ✘ Testing cascade
- ✘ Turn around time
- ✘ Labour intensive
- ✘ Medical waste
- ✘ Contamination risk
- ✘ Storage space intensive
- ✘ No EQA
- ✘ How does one validate
- ✘ Using up the whole sputum specimen



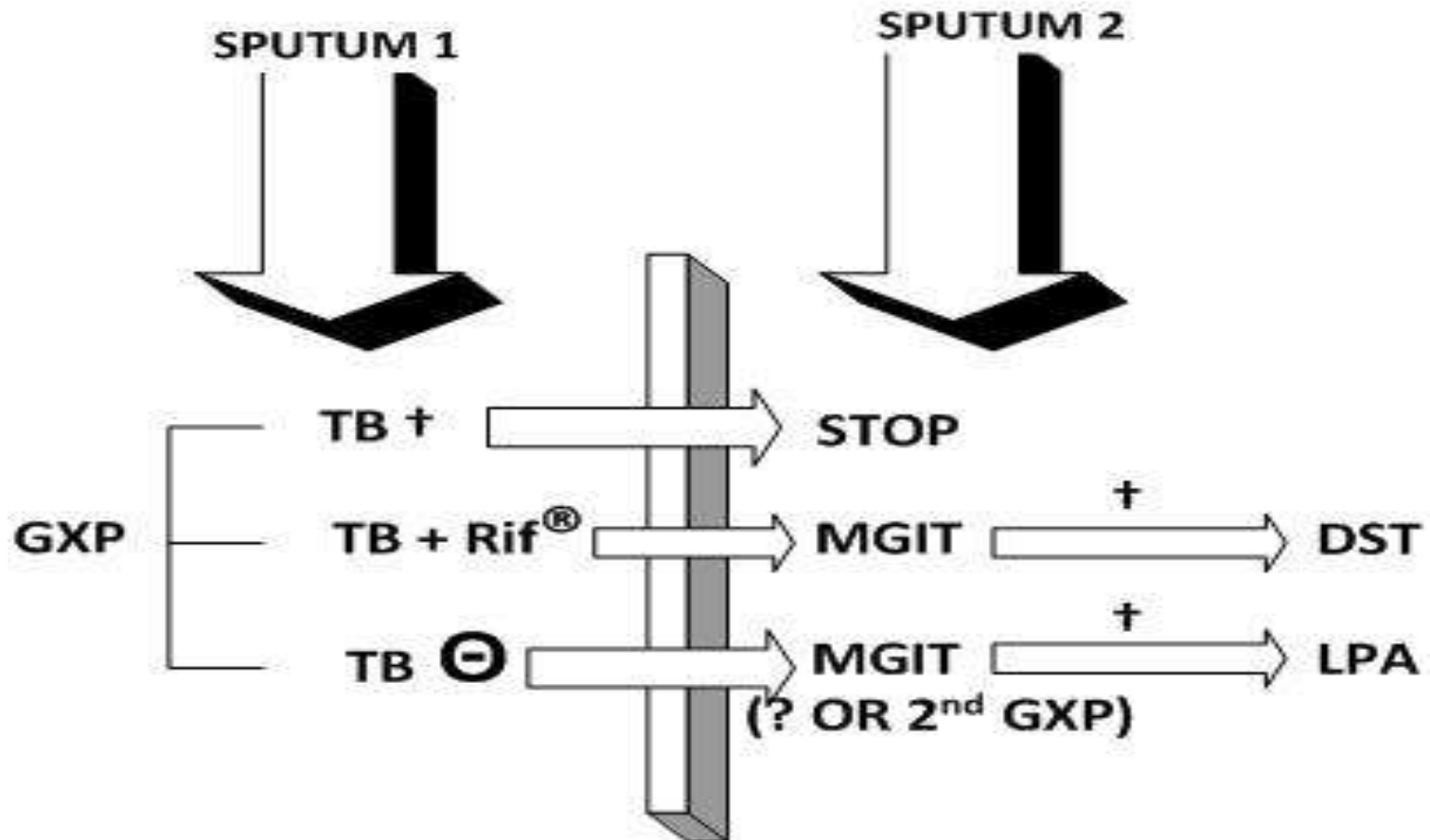
ALGORITHM FOR EARLY DETECTION OF MDR TB





DROPPING THE SMEAR

2 FRONTLOADED SPUTUM SPECIMENS








IDENTICARE


PATIENT MANAGEMENT SYSTEM



IDENTICARE

PATIENT MANAGEMENT SYSTEM

Healthcare Worker Home

Welcome Jane Doe (PETV09H00028) 


Petrouville Clinic - Appointment Summary

● Pending
 ● Successful
 ● Late
 ● Missed
 ● Treatment In
 ● Hold

Last Week		Today		This Week			Next Week		Totals		
●	●	●	●	●	●	●	●	●	●	●	●
0	0	1	0	1	0	1	1	0	0	0	0

Patient Login

Place patient's finger on the fingerprint scanning device




OR


Enter a patient identifier and press the login button


Rebert Code


OR


SA ID Number / Passport Number


LOGIN 


 CONSULTATIONS


 APPOINTMENTS


 TEST REQUESTS


 PATIENT SEARCH

 FACILITY SEARCH

 LOGOFF

 PATIENT REGISTRATION

 HEALTHCARE WORKER REGISTRATION

 EDIT MY DETAILS

BIOMETRIC IDENTIFICATION

IDENTICARE
PATIENT MANAGEMENT SYSTEM

IDENTICARE
PATIENT MANAGEMENT SYSTEM







✘ Interface written and delivered

+v16.04

✘ Label printers





- ✘ QC
 - + Quantified by flow cytometry to 10^4 /ml
 - + Inactivated and spotted on filter paper
- ✘ Sites (provisional)
 - Klerkdorp/Thsepong (with 4 satelites)
 - Welkom
 - Tugela Ferry
 - Polokwane
 - Bombela (satelite)
 - TAH
 - Umtata
 - Upington
 - Khayelitsha
 - Malmesbury ID
 - CHBaragwanath with Soweto satelites





THANK YOU