



# INTRODUCTION OF BPAL-L 6-MONTH RR-TB REGIMEN WEBINAR

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## REVISED TB DIAGNOSTIC ALGORITHMS

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30 August 2023

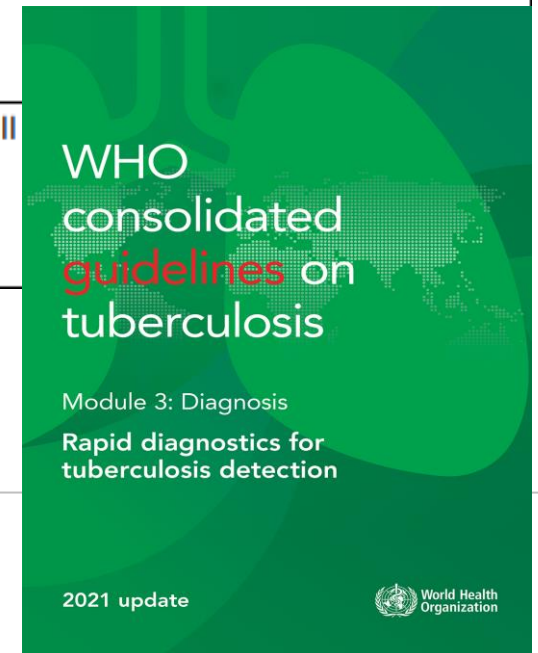
# OUTLINE

- Background to the changes
- New diagnostic platforms
- Placement
- Implications
- Diagnostic Algorithm revisions
- Way forward

# BACKGROUND

- Xpert cartridge shortages experienced in 2021-22
- Diversification of testing platforms
- WHO Update on the use of nucleic acid amplification tests to detect TB and drug-resistant TB

Technology Class	Products included in evaluation
Moderate complexity automated NAATs for detection of TB and resistance to rifampicin and isoniazid	Abbott RealTime MTB and Abbott RealTime MTB RIF/INH (Abbott) FluoroType MTBDR and FluoroType MTB (Hain Lifescience) BD MAX™ MDR-TB (Becton Dickinson) cobas MTB and cobas MTB-RIF/INH (Roche)
Low complexity automated NAATs for detection of resistance to isoniazid and second-line anti-TB agents	Xpert MTB/XDR (Cepheid)
High complexity hybridization-based NAATs for detection of resistance to pyrazinamide	Genoscholar PZA-TB II



# TB TESTING PLATFORMS

**GENEXPERT (CEPHEID)**



**COBAS MTB and COBAS MTB  
RIF/INH (ROCHE)**



**BD MAX MDR-TB (BECTON  
DICKINSON)**



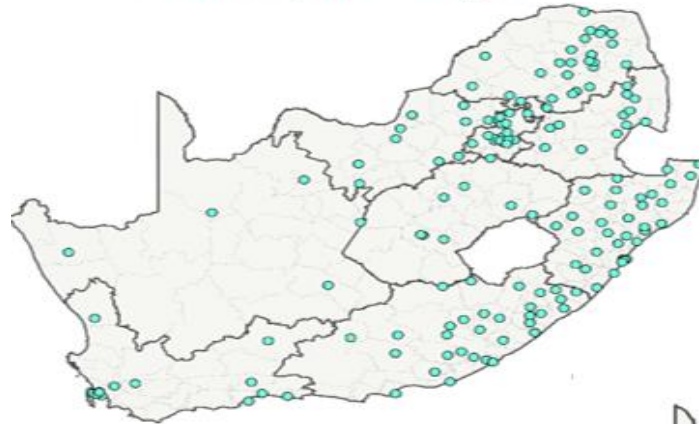
# PLACEMENT OF TESTS

DR-TB reflex testing will be conducted in the 15 culture and LPA laboratories

Changing landscape with moderate-complexity platforms:

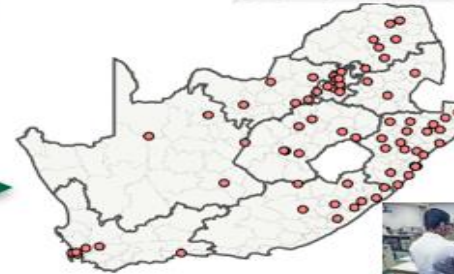
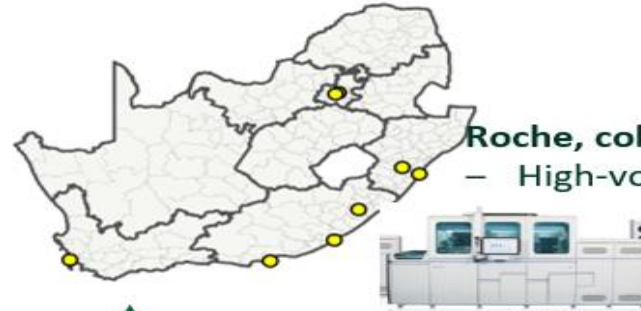
**Existing Xpert footprint:**

- n=162
- High, medium and low-volume processing sites



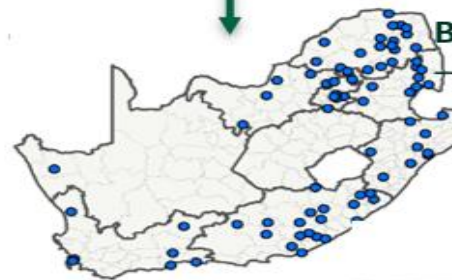
**Roche, cobas 6800/8800:**

- High-volume sites, n=8



**Becton Dickinson, BDMAX:**

- Medium -volume sites, n=75



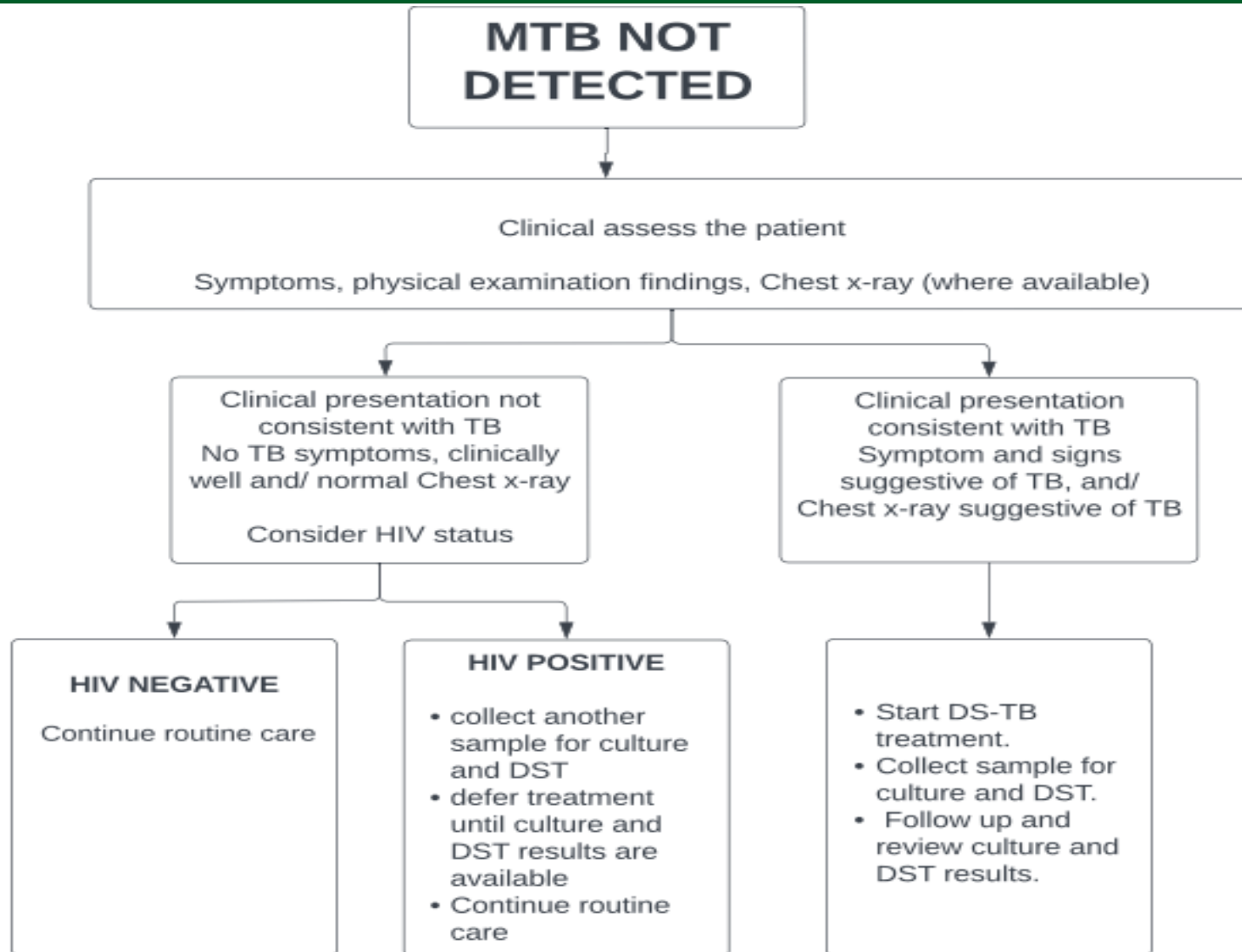
**Cepheid**

- Low-volume sites, n=79

# IMPLICATIONS

- No reference to Xpert as first line test but TB-NAAT which is the class of all these tests
- Cobas and BD Max conducted on sputum only
- Xpert conducted on sputum, gastric washings/aspirates, lymph node biopsies or fine needle aspirates, tissue biopsies, Fluids (joint, pleural, ascitic, peritoneal, pus collection) and cerebro-spinal fluid (CSF) – ? stool, urine
- Results reported as RS, RR, HR, MDR TB
- Major change is HR diagnosis upfront, requiring appropriate management at point of diagnosis
- Patients with RR/MDR-TB will be referred to treatment initiation site

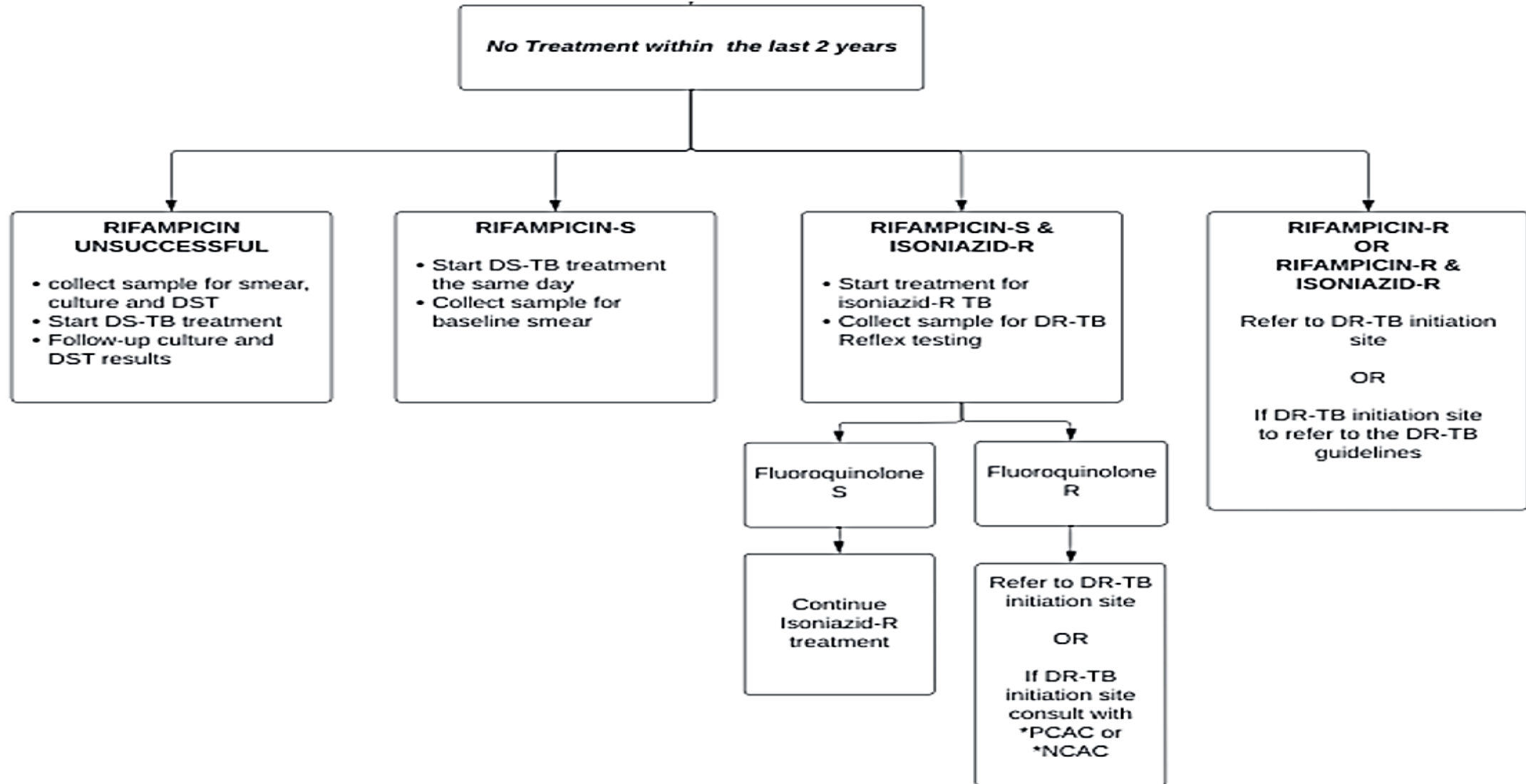
# MTB NOT DETECTED



**TEST UNSUCCESSFUL**

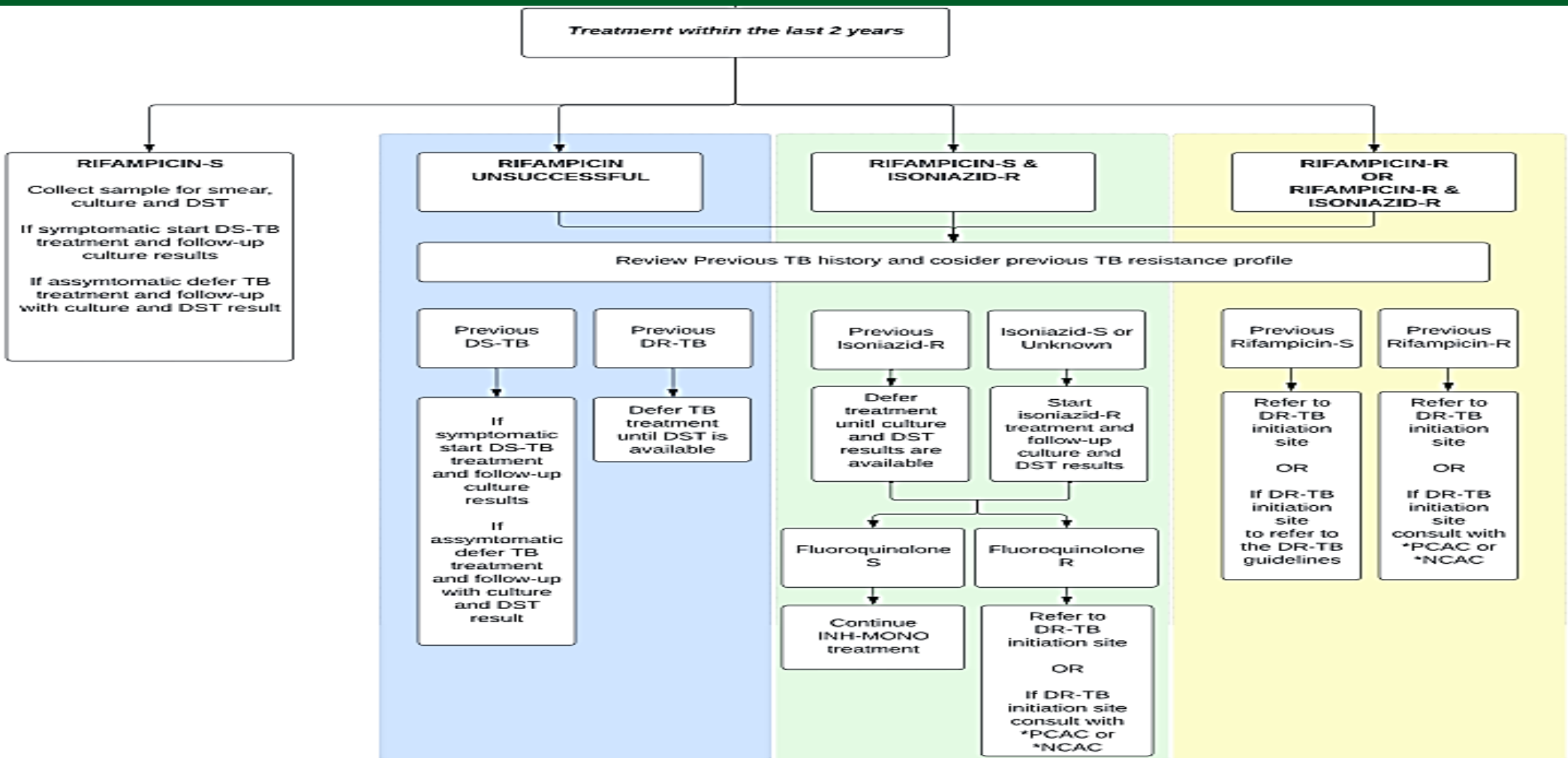
Collect another sample for  
TB-NAAT

# MTB DETECTED – NO TREATMENT WITHIN THE LAST 2 YEARS

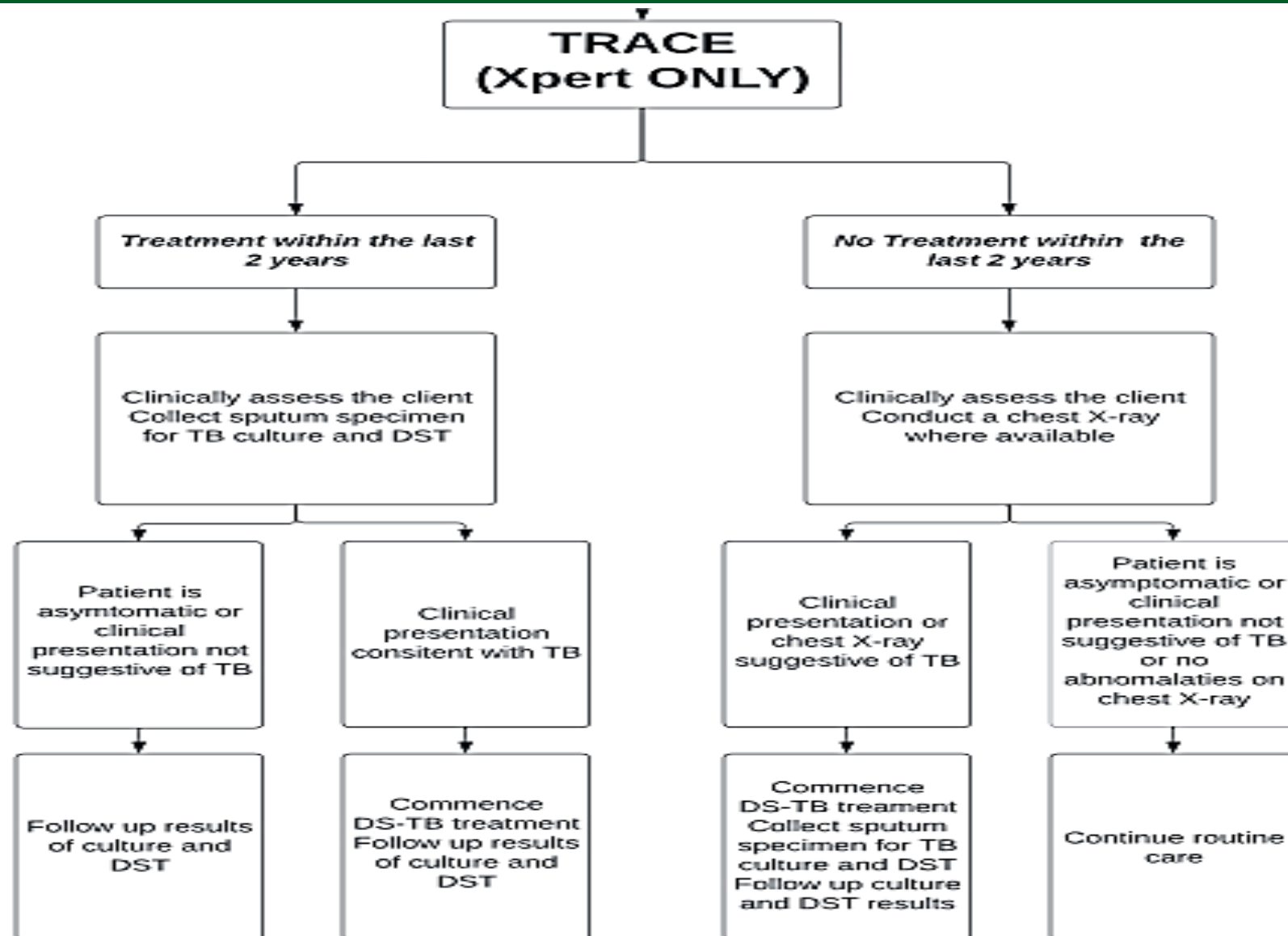




# MTB DETECTED – TREATMENT WITHIN THE LAST 2 YEARS



# TRACE (Xpert ONLY)



health

Department:  
Health  
REPUBLIC OF SOUTH AFRICA



# WAY FORWARD

- Implementation in September dependent on laboratory readiness
- Laboratory reports will be revised
- Training
- Knowledge Hub webinars
- Printing and dissemination of algorithms
- Revision of data elements and NIDS

thank  
you