

# Point of care solutions for tuberculosis diagnosis

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# True**l**ab Workstation

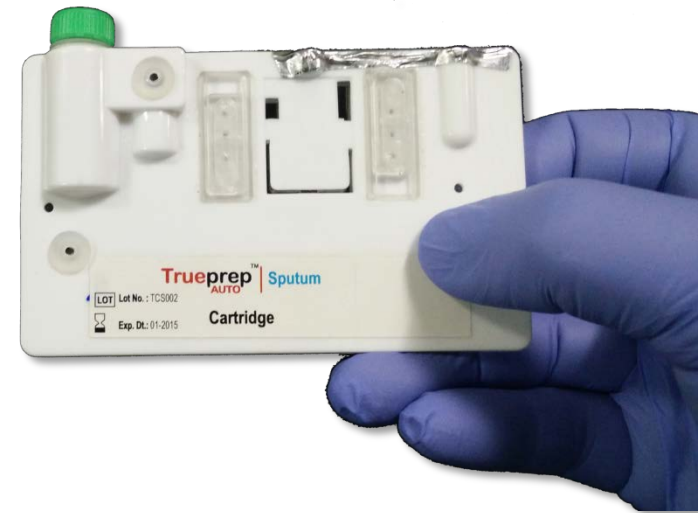
Any Where, Any Time, Real Time PCR

- Infrastructure independent
- All devices are portable, rechargeable battery powered
- Complete package with microPCR, Sample prep, Printer, pipettes & chargers



The True Game Changer !

# Trueprep™ AUTO

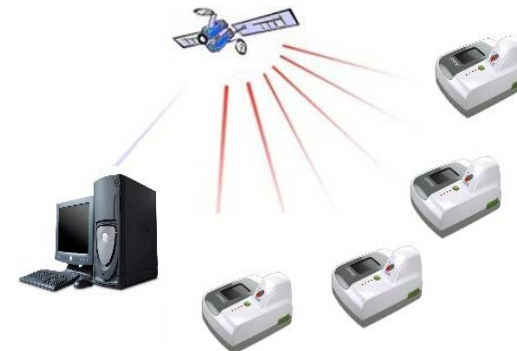


**Battery powered, portable, automated sample prep for sputum.  
12 minutes per prep, 18 runs per re-charge.**



**Truenat MTB & Truenat MTB RIF:**  
Ready to use smart chips: TB case  
detection and Rif resistance  
detection

Real time quantitative microPCR system.  
Battery powered and portable.  
Built-in network data transfer ability



Centralized monitoring / automated surveillance

# Truenat™ MTB

## Result screens

Truenat™ MTB				
Center				
Date	Tue 01 Jul 2014 10:01			
Operator	Service			
Profile	MTB			
Lot	M0513	Expiry Date	04-15	
Sample	Sputum			
Patient Details				
Name	john			
ID	1123			
Age	35	Sex	Male	
Referred By	chirstopher			
Result				
Run Status	Valid			
MTB	DETECTED Medium			
Print	SMS	Email	Share	Back

Truenat™ MTB				
Center				
Date	Tue 01 Jul 2014 07:21			
Operator	Service			
Profile	MTB			
Lot	M0513	Expiry Date	04-15	
Sample	Sputum			
Patient Details				
Name	john			
ID	1123			
Age	35	Sex	Male	
Referred By	chirstopher			
Result				
Run Status	Valid			
MTB	NOT DETECTED			
Print	SMS	Email	Share	Back

Auto interpretation and text read out of results

Full Internal positive control (sample prep to PCR) based test validity

# Validations

- World wide TB strain coverage: Strain Bank from the Institute of Tropical Medicine in Antwerp, Belgium (235 strains)
- NTM exclusivity: Confirmed with NTM Panel from Hinduja hospital, Mumbai
- Clinical evaluations: 2 studies at Hinduja hospital Mumbai
- Studies initiated / on-going:
  - FIND/CDRC: South Africa, Uganda and Brazil
  - ICMR: 4 centers in India

# MTB: Clinical evaluation 1

OPEN ACCESS Freely available online

PLOS ONE

## Rapid Diagnosis of *Mycobacterium tuberculosis* with Truenat MTB: A Near-Care Approach

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### Abstract

**Background:** Control of the global Tuberculosis (TB) burden is hindered by the lack of a simple and effective diagnostic test that can be utilized in resource-limited settings.

**Methods:** We evaluated the performance of Truenat MTB™, a chip-based nucleic acid amplification test in the detection of *Mycobacterium tuberculosis* (MTB) in clinical sputum specimens from 226 patients with suspected pulmonary tuberculosis (TB). The test involved sputum processing using Trueprep-MAG™ (nanoparticle-based protocol run on a battery-operated device) and real-time PCR performed on the Truelab Uno™ analyzer (handheld, battery-operated thermal cycler). Specimens were also examined for presence of MTB using smear microscopy, liquid culture and an in-house nested PCR protocol. Results were assessed in comparison to a composite reference standard (CRS) consisting of smear and culture results, clinical treatment and follow-up, and radiology findings.

**Results:** Based on the CRS, 191 patients had “Clinical-TB” (Definite and Probable-TB). Of which 154 patients are already on treatment, and 37 were treatment naïve cases. Remaining 35 were confirmed “Non-TB” cases which are treatment naïve cases. The Truenat MTB test was found to have sensitivity and specificity of 91.1% (CI: 86.1–94.7) and 100% (CI: 90.0–100) respectively, in comparison to 90.58% (CI: 85.5–94.3) and 91.43% (CI: 76.9–98.2) respectively for the in-house nested PCR protocol.

**Conclusion:** This preliminary study shows that the Truenat MTB test allows detection of TB in approximately one hour and

**N= 226**

**99% sensitive in smear+ culture + specimens (111/112)**

**76% sensitive in smear– culture + specimens (22/29)**

**Specificity in “Non-TB” cases (based on CRS) = 100% (35/35)**



# MTB: Clinical evaluation 2



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## Evaluation of the Indian TrueNAT micro RT-PCR device with GeneXpert for case detection of pulmonary tuberculosis

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### ARTICLE INFO

Article history:

### ABSTRACT

To evaluate the performance of TrueNAT (RT Micro PCR device) assay in comparison with

S+C+ category:

Xpert sensitivity: 100%

Truenat MTB sensitivity: 98.9%

S-C+ category:

Xpert sensitivity: 90.1%

Truenat MTB sensitivity: 86.8%

Using Xpert as reference standard;

Sensitivity: 96.1%

Specificity: 95.6%

Total Samples: 274

# Truelab™ @ point of care: True impact in health care



Truelab workstation being used for Malaria (*P. fal*) study at Gobei Health Centre, Kenya