



The FIND TB diagnostic portfolio: does it address the need

Mark Perkins
CSO, FIND

IUATLD, October 2008, Paris

Partnering for better diagnosis for all

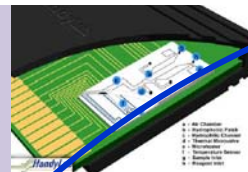
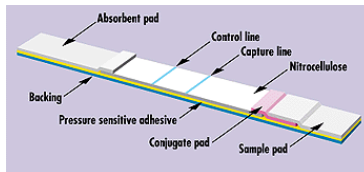
Situation in 2004

- No new TB tests in public sector for many years
- No WHO approval mechanism
- No dedicated laboratory strengthening initiative
- No mechanism to link policy change to scaled-up implementation
- No DEC pricing mechanism for existing tools
- No public sector platform for discovery and development of new TB tests

Situation in 2008

- Multiple new TB tests in public sector use
- WHO approval mechanism established
- Global laboratory initiative established/Maputo declaration
- UNITAID, PEPFAR, GFATM funding scale-up
- Negotiated pricing in place
- Multiple discovery and development activities led or partnered with the public sector

FIND board Feb 2004

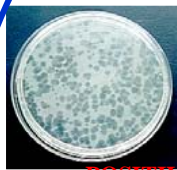


Tests that revolutionize patient care or disease control

- POC smear replacement
- POC culture replacement
- 2-day high-TP sensitive lab test for case detection +/- DST for urban centers
- 2-day lab-free culture replacement
- Specific predictor of progression from LTBI

short-term

Tests that are significant incremental improvements over existing tools



POSITIVE



- Improved microscopy
- Simplified or speeded culture
- Simplified or speeded DST

2004

2005

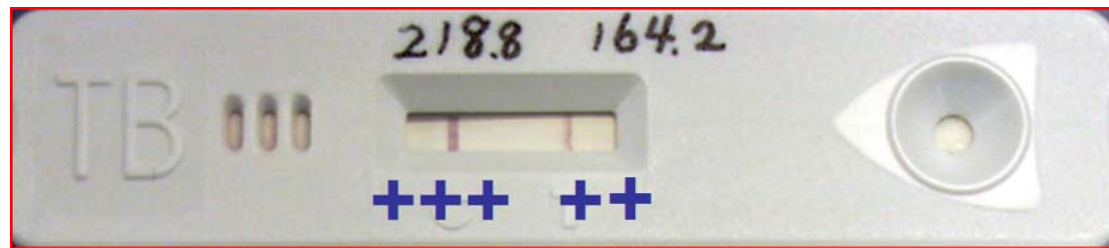
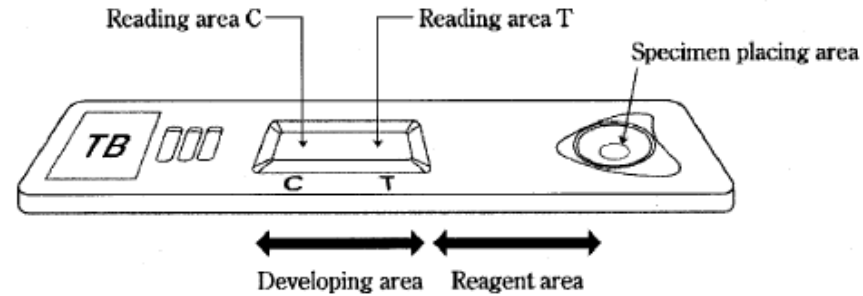
2006

2007

2008

2009

Addressing equity: Making EME standard accessible in DEC



- Price negotiations on MGIT
- Licensing agreement for MPT64
- Development for lower cost version
- Large demonstration projects (>100,000 pts)
- Customer support plan

Addressing MDR crisis: Proving PCR and line-probe hybridization in HBCs



May 2004 Peru study of 5 methods

Test, method	Total cost ^a for 1000 patients, by prevalence of Rif resistance				Average cost per case detected, by prevalence of MDR TB			
	50%	20%	5%	2%	50%	20%	5%	2%
Detection of Rif resistance								
IDLJ	-327,321	-73,259	53,772	79,178	-668	-374	1098	4041
FASTPlaque-Response	-369,360	-66,754	84,549	114,810	-793	-358	1815	6162
INNO-LiPA	-334,473	-54,727	85,146	113,121	-728	-298	1853	6155
DLJ	-382,584	-120,655	10,310	36,503	-822	-648	222	1962
MTT assay	-365,343	-114,088	11,540	36,665	-898	-701	284	2253
Detection of multidrug resistance								
IDLJ	-324,287	-70,226	56,805	82,211	-662	-358	1159	4111
FASTPlaque-Response	-345,420	-29,523	128,426	159,991	-749	-160	2785	8672
INNO-LiPA	-317,385	-26,957	118,257	147,309	-688	-146	2564	7985
DLJ	-369,745	-103,402	29,769	56,404	-795	-556	640	3031
MTT assay	-337,908	-75,027	56,414	82,646	-842	-468	1406	5150

Addressing MDR crisis: Proving PCR and line-probe hybridization in HBCs

Press Release: 9 October 2006

FIND and Hain Lifescience agree to fast track a rapid molecular screening test for MDR and XDR tuberculosis



Addressing MDR crisis: Proving PCR and line-probe hybridization in HBCs



2007 Evaluation of Genotype MDRTB plus

- 536 patients included

	Rifampicin	Isoniazid	Multidrug-resistance
Sensitivity	98.9% (94.3 – 100.0)	94.2% (88.4 – 97.6)	98.8% (93.7 – 100.0)
Specificity	99.4% (98.0 – 100.0)	99.7% (98.3 – 100.0)	100% (99.0 – 100.0)
Overall accuracy	99.3% (98.1 – 99.9)	98.2% (96.5 – 99.2)	99.8% (98.8 – 100.0)
PPV	97.9% (92.7 – 99.7)	99.1% (95.3 – 100.0)	100% (95.8 – 100.0)
NPV	99.7% (98.4 – 100.0)	97.9% (95.7 – 99.2)	99.7% (98.5 – 100.0)

- 97% specimens gave interpretable results, including 95% of specimens with contaminated MGIT cultures

Addressing MDR crisis: Proving PCR and line-probe hybridization in HBCs

Officials Praise New Test for Drug-Resistant TB

By LAWRENCE K. ALTMAN
Published: July 1, 2008

A new test that can detect multiple-drug-resistant tuberculosis in two days instead of the standard two to three months promises to help significantly improve treatment and prevent the spread of the airborne infection, the [World Health Organization](#) said on Monday.

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Salvatore Di Nolfi/European Pressphoto Agency

Experts discussed multiple-drug-resistant tuberculosis at a news conference Monday in Geneva. Dr.

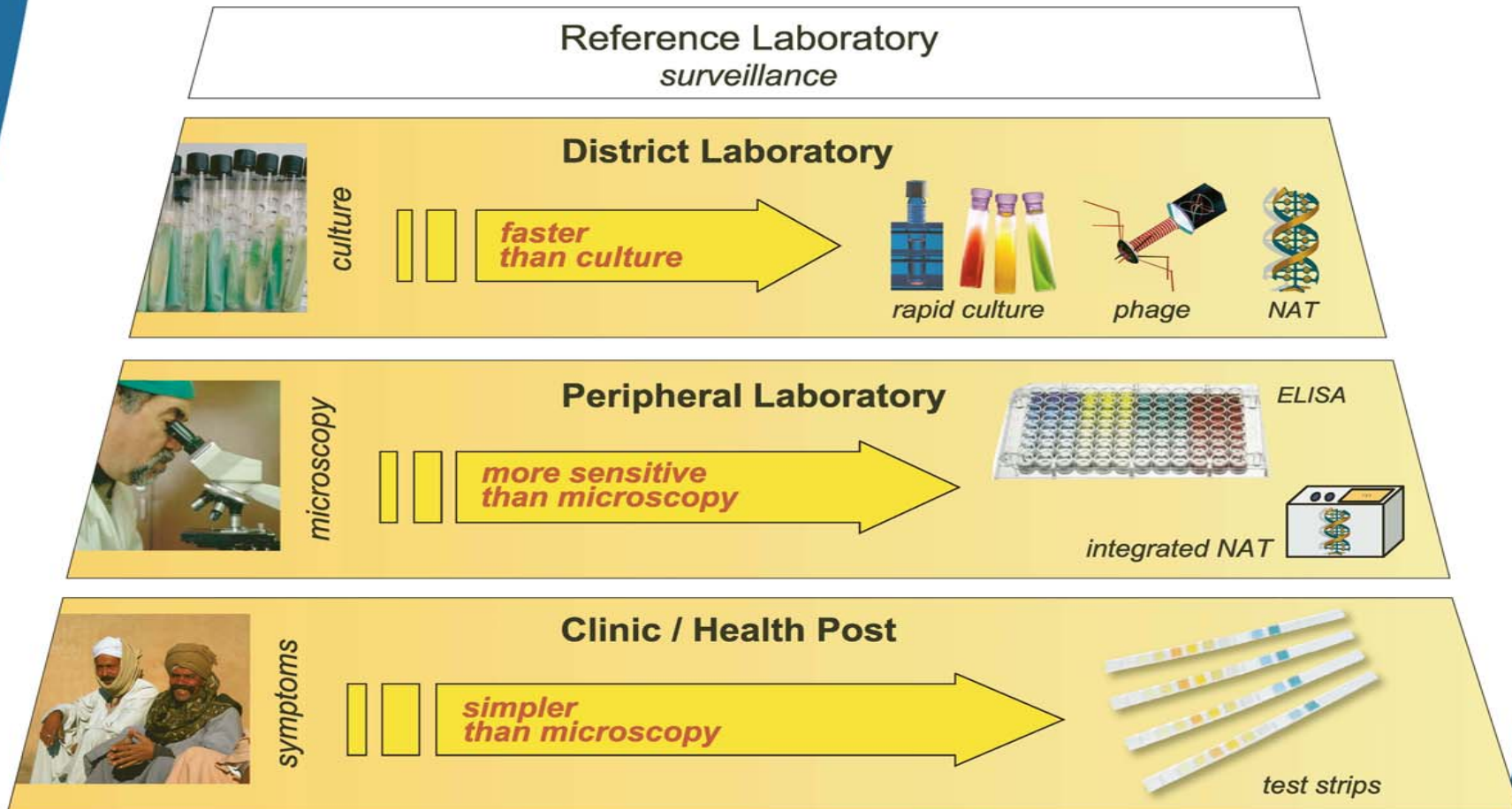
Multiple-drug-resistant TB, or MDR-TB, is a growing public health problem in the world. Five percent of new TB cases are resistant to first-line drugs. That is 450,000 of the nine million new TB cases that are detected each year, the W.H.O. says.

In the United States, the prevalence of drug-resistant tuberculosis among foreign-born TB patients has been about 1.5 percent, roughly three times the percentage among American-born patients with TB.

The new test was described for reporters by telephone on Monday by officials from the W.H.O. and three other international health groups, the Stop TB Partnership, Unitaid and the Foundation for Innovative New Diagnostics, or FIND.

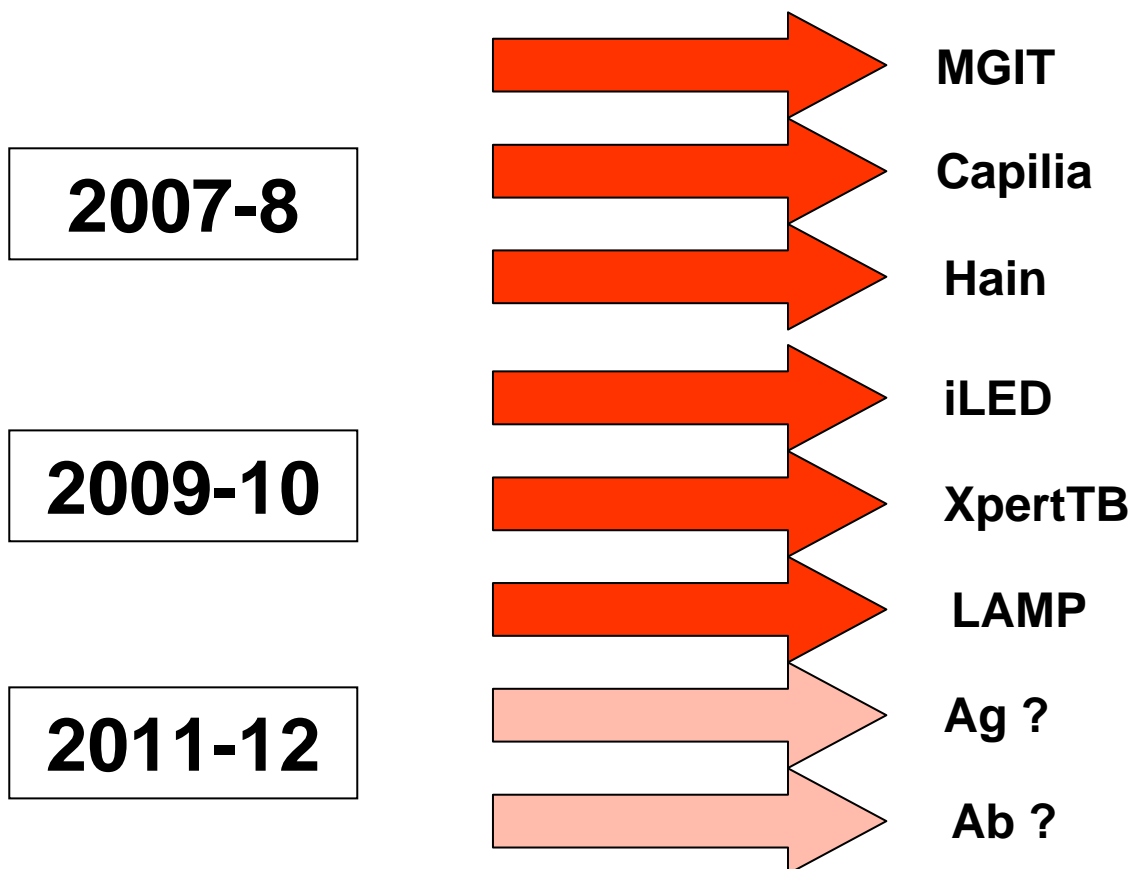
The New York Times

Diagnostic needs at different levels of the health system



today

tomorrow



today

tomorrow

Point of care testing



- Antigen detection
 - Feasibility studies of Ag detection in sputum
 - Evaluations of commercial LAM
 - Development of new LAM reagents
 - MS characterization of LAM species in urine
 - Proteomic discovery from urine, sputum, blood
 - Feasibility studies of more sensitive POC platforms
- Volatiles detection
 - Feasibility studies of eNose
 - VOC discovery projects
- Antibody detection
 - Screening entire proteome
 - Alternate expression systems
 - Peptide profiling
- Molecular testing
 - Feasibility assessment of POC molecular
 - Feasibility studies of trans-renal DNA
- **New approaches**
 - **FIND RFA for POC 2008**