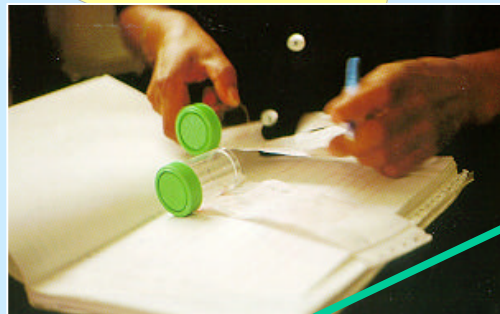


# FASTPlaqueTB – a practical aid for the rapid diagnosis of TB in low income countries

Muzaffar R<sup>1</sup>, \*Mole R<sup>2</sup>, Albert H<sup>3</sup>, Harley B<sup>4</sup>, Subotzky E<sup>4</sup>, Henry R<sup>4</sup>, Azevedo V<sup>4</sup>.

<sup>1</sup> Sindh Institute of Urology and Transplantation, Karachi, Pakistan, <sup>2</sup> Biotec Laboratories Ltd., Ipswich, UK, <sup>3</sup> Biotec Laboratories Ltd., Johannesburg, South Africa, <sup>4</sup> South Peninsula Administration, Cape Town, South Africa.

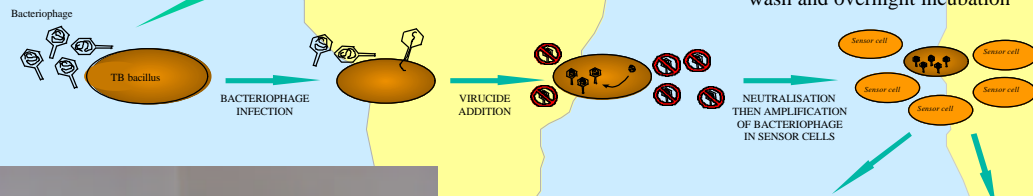
The FASTPlaqueTB assay is a novel tuberculosis diagnostic test based on Phage Amplification technology. The test is easy to operate and requires only basic microbiological equipment. Results are available within 2 days. The test is based on the ability of a bacteriophage to specifically infect viable MTB bacilli in decontaminated sputum specimens. After the infection period, bacteriophage then “report” the presence of infected cells by the release of progeny phage detected as zones of clearing in lawns of susceptible, rapidly growing non-pathogenic host cells.



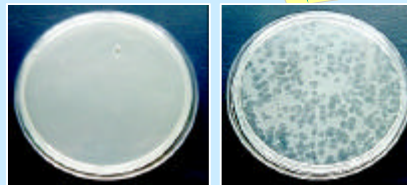
Sputum collection



NALC-NaOH treatment followed by additional wash and overnight incubation



FASTPlaqueTB kit



If no target MTB then <20 plaques seen  
Negative result

If MTB present then >20 plaques seen  
Positive result

The FASTPlaqueTB assay has been evaluated at several locations in Asia, Africa and Europe since 2000. In addition to several smaller evaluations, three large-scale studies have been completed. These studies provide an insight into the performance of this test in a range of geographical locations and settings.

Published results from three large scale studies and un-published data from a range of smaller scale studies have compared the performance of the FASTPlaqueTB test to culture (both solid and liquid culture systems) and has demonstrated that the test performs consistently well across a range of settings. In each study, specificity was extremely high (>97%), giving a high degree of confidence that a positive FASTPlaqueTB result was representative of active disease. High specificity was reported even in the presence of a high number of non-tuberculous mycobacterial isolates in the population studied (up to 32%)<sup>2</sup>. Overall the test detected 65-83% of confirmed TB cases within two days, compared to culture, which took up to eight weeks.

	Cape Town, South Africa (n=1618) <sup>1</sup>	Barcelona, Spain (n=857) <sup>2</sup>	Karachi, Pakistan (n=514) <sup>3</sup>	Small scale evaluations (n=441)*
Specificity (%)	99.0	98.5	97.7	97.4
Sensitivity (%)	72.5	64.6	81.6	83.4
PPV	0.91	0.78	0.97	0.95
NPV	0.96	0.97	0.85	0.90

\* Seven separate studies (mean n = 63, n range = 19 - 141) conducted in India (3), Pakistan, Egypt, Kenya and Zimbabwe

## FASTPlaqueTB features

- Rapid 2 day assay for detection of viable TB bacilli in sputum
- Highly specific (>97%) for the detection of MTB
- Functions well even with high MOTT incidence populations and populations with HIV
- Sensitivity (65-83%) consistent over a number of trials
- Detects TB positive cases missed by smear
- Aids in the diagnosis of TB from sputum, in particular smear negative specimens
- Requires only basic microbiology equipment and expertise
- Supplied as kit with all reagents necessary to perform detection assay

## Future developments to

- Diagnose TB in children and from extra-pulmonary samples
- Detect rifampicin resistance directly from sputum in 2 days

## References

1. Albert H. *et al.* Performance of a rapid phage-based test, FASTPlaqueTB™, to diagnose tuberculosis from sputum specimens of TB suspects. *Int J. Tuberc. & Lung Dis.* 6 (6) 529-537, 2002
2. Orús, P. *et al.* Usefulness of a New Mycobacteriophage-Based Technique for the Rapid Diagnosis of Pulmonary Tuberculosis. 11th European Congress of Clinical Microbiology and Infectious Diseases, Istanbul, 2001
3. Muzaffar R. *et al.* Evaluation of the FASTPlaqueTB™ assay for direct detection of *Mycobacterium tuberculosis* in sputum specimens in Pakistan. *Accepted. Int J. Tuberc. & Lung Dis.* July 2002

\*Corresponding address: Biotec Laboratories Ltd., 38 Anson Road, Martlesham Heath, Ipswich, IP5 3RG, UK. Tel : +44 1473 612158, Fax : +44 1473 611476, Email: richard.mole@biotec.com