

Evaluation of *FASTPlaqueTB-RIF*TM, a rapid, manual test for the determination of rifampicin resistance from *Mycobacterium tuberculosis* cultures

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SUMMARY

SETTING: Two Mycobacteriology Reference Laboratories in Johannesburg (Laboratory 1) and Cape Town (Laboratory 2), South Africa.

OBJECTIVE: To determine the ability of the *FAST-PlaqueTB-RIF*TM test to correctly identify rifampicin susceptibility on strains of *Mycobacterium tuberculosis* cultured on solid media.

DESIGN: A comparative study of *FASTPlaqueTB-RIF*TM and conventional drug susceptibility methods, with selection bias to include sufficient rifampicin resistant strains.

RESULTS: Rifampicin susceptibility results were available for 191 strains of *M. tuberculosis*. Eighty-one strains were found to be rifampicin resistant and 110 strains were rifampicin susceptible by conventional meth-

ods. The sensitivity, specificity and overall accuracy for the *FASTPlaqueTB-RIF*TM were 100%, 97% and 98% at Laboratory 1, and 100%, 94% and 97% at Laboratory 2.

CONCLUSION: *FASTPlaqueTB-RIF*TM offers a performance comparable to the gold standard proportion methods of rifampicin susceptibility testing, as well as the advantage of the speed of results that the newer methods deliver, without the need for specialised equipment. This makes *FASTPlaqueTB-RIF*TM a rapid test for rifampicin resistance suitable for widespread application.

KEY WORDS: rifampicin; mycobacteriophage; susceptibility test; tuberculosis; resistance

MULTIDRUG-RESISTANT tuberculosis (MDR-TB) is a world-wide problem.¹ Multidrug resistance usually refers to resistance of a strain of *Mycobacterium tuberculosis* to at least two of the commonly used tuberculosis drugs. In practice, MDR-TB often refers to resistance to the most effective anti-tuberculosis drugs, isoniazid and rifampicin. Testing the rifampicin susceptibility of clinical isolates of *M. tuberculosis* can have important benefits for both the patient and the community at large. Recently, rifampicin resistance has been identified as a good predictor of MDR-TB in many parts of the world. For example, in studies conducted in Estonia, Ethiopia, India (Delhi State) and Latvia, of the total number of rifampicin-resistant strains, 100%, 100%, 95% and 96% respectively of the strains were MDR-TB (resistant to at least rifampicin and isoniazid).^{1,2} Determination of the susceptibility of a clinical isolate of *M. tuberculosis* to rifampicin will identify those patients most likely to fail standard treatment regimens. Delay of appropriate treatment can lead to both more serious disease and additional opportunities for dissemination.

Early detection of MDR-TB can improve treat-

ment regimens. As conventional susceptibility testing takes 3–4 weeks, there is a significant delay in patients receiving appropriate treatment. Of the rapid, automated culture-based susceptibility methods that have been developed,^{3–5} the Bactec 460 radiometric method (Becton Dickinson, Sparks, MD, USA) is widely used. However, due to the high reagent cost and need for expensive, specialised equipment, such methods are often unsuitable for many laboratories, especially those located in low-income countries.

The proportion method is commonly used for conventional drug susceptibility testing of *M. tuberculosis*.⁶ The Centers for Disease Control and Prevention in the United States recommends the use of Middlebrook 7H10 or 7H11 medium, while the World Health Organization and the International Union Against Tuberculosis and Lung Disease recommend the use of Löwenstein-Jensen (LJ) medium. The LJ proportion method is the most widely used method worldwide.⁷ Regardless of the medium used, the proportion method is considered the gold standard in drug susceptibility testing of *M. tuberculosis*.³

The *FASTPlaqueTB-RIF*TM Rifampicin Suscepti-

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bility Test (Biotec Laboratories Ltd, Ipswich, UK) is a manual test for the rapid determination of rifampicin susceptibility of *M. tuberculosis* cultures within 48 hours. This test utilises specific mycobacteriophage (Actiphage™) to reflect the presence of viable *M. tuberculosis*.⁸⁻¹² After phage infection, a virucidal solution (Virusol™) destroys all phage that have not infected the tubercle bacilli. The phage replicate in the infected bacilli until new progeny phage are released as the cells lyse. The new phage are amplified by the addition of a non-pathogenic rapid-growing mycobacterial host, *M. smegmatis* (Sensor™ cells), which is also able to support phage replication. Phage can be visualised as clear areas (plaques) in a lawn of Sensor™ cells. The number of plaques visualised from a given sample is related to the number of viable tubercle bacilli in the original sample.

In the *FASTPlaqueTB-RIF™* test, the number of plaques in a rifampicin-free control is compared with the number of plaques produced from a sample incubated in the presence of rifampicin. The absence of plaques in the rifampicin-containing sample indicates that the strain is sensitive to rifampicin (i.e., the tubercle bacilli are no longer viable and can not support phage replication). The presence of plaques in the rifampicin-containing sample indicates that viable tubercle bacilli have survived (and can support phage replication), and that the strain is resistant to rifampicin.

This study compares the ability of the *FASTPlaqueTB-RIF™* test to correctly identify rifampicin susceptibility in strains of *M. tuberculosis* cultured on solid medium. Comparisons were performed at two centres against the indirect proportion method using 7H11 and LJ medium and the Bactec 460 radiometric method.

MATERIALS AND METHODS

Cultures

Cultures were prepared from sputum received from 195 patients for routine diagnosis of tuberculosis and drug susceptibility testing by the TB Laboratory, South African Institute for Medical Research, located in either Johannesburg (Laboratory 1, $n = 98$) or Cape Town (Laboratory 2, $n = 97$). The Figure shows a diagrammatic representation of the testing performed in Laboratories 1 and 2. Selection of cultures for this study was biased to allow inclusion of sufficient rifampicin-resistant strains. Only one specimen per patient was submitted to the study.

Laboratory 1

Primary isolation of *M. tuberculosis* from clinical specimens was performed using a modified Petroff's method (4% sodium hydroxide), and both Bactec 460 and LJ culture methods. Positive cultures were confirmed as *M. tuberculosis* by use of an in-house PCR method (MPB64) and Ziehl-Neelsen (ZN) stain-

ing. Conventional rifampicin susceptibility testing was performed on positive Bactec 12B cultures using the Bactec drug susceptibility test as recommended by the manufacturer. The final concentration of rifampicin tested was 2.0 µg/ml.¹³ In addition, the simplified variant of the indirect proportion method (using a single drug concentration) was performed from the primary Bactec 12B culture on Middlebrook 7H11 agar, using 1.0 µg/ml rifampicin.⁴

The clinical performance of *FASTPlaqueTB-RIF™* was evaluated by comparing the results with two routinely-used rifampicin susceptibility test methods. Inocula for *FASTPlaqueTB-RIF™* testing were prepared from positive LJ cultures (primary isolation of *M. tuberculosis* from a clinical specimen) or from a positive control (drug-free) Middlebrook 7H11 culture prepared as part of the routine Middlebrook 7H11 susceptibility test.

Laboratory 2

The clinical performance of *FASTPlaqueTB-RIF™* was assessed by comparison of the *FASTPlaqueTB-RIF™* results with the LJ proportion method. Primary isolation of *M. tuberculosis* from clinical specimens was performed using the N-acetyl L-cysteine sodium hydroxide method and the Bactec 460 culture method. Identification of *M. tuberculosis* was carried out by niacin testing and ZN staining. Positive BACTEC 12B vials were used for preparation of inocula for the LJ susceptibility testing. The simplified variant of the indirect proportion method (using a single drug concentration) was performed using 30 µg/ml rifampicin in LJ medium.⁶ A sample was taken from each positive control (drug-free) LJ slope (prepared as part of the LJ susceptibility test), for testing by *FASTPlaqueTB-RIF™*.

Proportion method

A standardised inoculum of the test strains was prepared directly from the BACTEC 12B vial once the growth index had reached 800. For the rifampicin susceptibility test on Middlebrook 7H11 agar, a 1:100 dilution was prepared in Middlebrook 7H9 broth, and 0.1 ml of this suspension was used to inoculate the control and test media. The Middlebrook 7H11 plates were sealed in a polypropylene bag, and were incubated in 5% CO₂ at 37°C for 3 weeks. For the rifampicin susceptibility test on LJ medium, a 1:100 dilution was prepared in a 0.1% Tween 80 in distilled water, and 0.1 ml of this suspension was used to inoculate the control and test media. The LJ slopes were incubated for 4 weeks at 37°C. After incubation, the number of colonies on the drug-containing medium were expressed as a percentage of those on the drug-free medium. If more than 1% of the colonies were found to be resistant, the isolate was considered resistant to rifampicin in vitro.

Preparation of *M. tuberculosis* test suspensions for FASTPlaqueTB-RIF™ testing

The components of the FASTPlaqueTB-RIF™ were reconstituted according to the manufacturer's instructions and used on the day of reconstitution. Fresh cultures (up to 3 weeks old) on LJ or solid Middlebrook 7H11 media were used as a source of the organisms. Test suspensions were prepared using approximately 0.5 µl of *M. tuberculosis* growth. The growth was added to 5 ml FPTB Medium Plus in a sterile glass bijou bottle containing 6–8 glass beads. The suspension was homogenised using a vortex mixer for 15–20 seconds. Large clumps were allowed to settle by standing for 10–15 minutes and the supernatant fraction was removed for testing.

FASTPlaqueTB-RIF™ assay procedure

The FASTPlaqueTB-RIF™ assay procedure was carried out in a Class 2 bio-safety cabinet. Positive and negative assay controls were prepared and tested according to the manufacturer's instructions.

One rifampicin tablet (200 µg) was dissolved in 20 ml FPTB Medium Plus, and thoroughly mixed to ensure dissolution. The final concentration of rifampicin was 5 µg/ml; 0.5 ml of the rifampicin solution was dispensed into a reaction vessel (RIF+), 0.5 ml of FPTB medium was dispensed into another reaction vessel (RIF–), and 0.5 ml of the *M. tuberculosis* test suspension was added to both the RIF– and RIF+ reaction vessels. The vessels were gently shaken to mix and were incubated for 24 hours in a static incubator at 37°C.

The vessels were removed from the incubator and 100 µl of Actiphage™ was added. The samples were incubated at 37°C for 90 minutes without further mixing. One hundred microlitres of Virusol™ solution was added to the sample; the contents of the tube were mixed well by inverting and rolling the reaction vessel to ensure that the Virusol™ came into contact with all the interior surfaces of the vessel to allow efficient inactivation of all exogenous phage. The samples were allowed to stand at room temperature for 5 minutes; 5 ml of FPTB Medium Plus was added to the vessel and mixed by inverting the reaction vessel once, and then 1 ml of Sensor cells was added to each vessel. Five millilitres of molten FPTB Agar (at 50–55°C) was placed in an empty sterile disposable plastic Petri dish (90 mm), then the entire contents of the reaction vessel were added. The lid of the Petri dish was closed and the contents were mixed well, by swirling in both directions, ensuring that the entire bottom surface of the plate was covered. Care was taken to avoid agar splashing the lid of the Petri dish. The plates were allowed to set at room temperature. Once set, the plates were inverted and incubated at 37°C. After overnight (approximately 18–24 hours) incubation, the plates were removed and examined. The number of plaques on each plate was recorded.

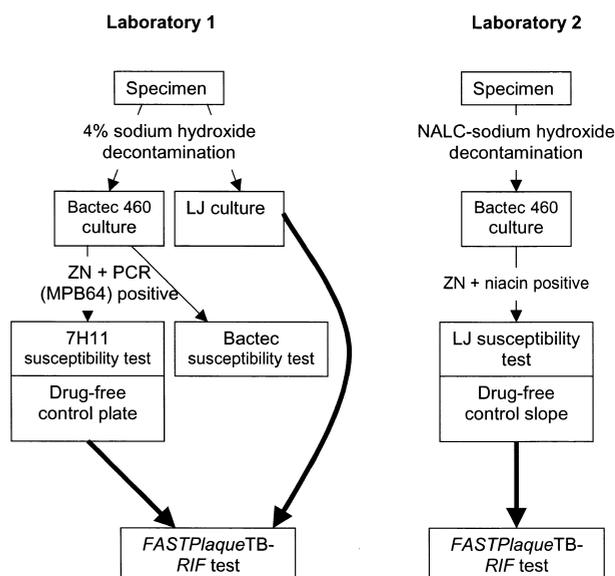


Figure Diagrammatic representation of the workflow in Laboratory 1 and 2. LJ = Löwenstein-Jensen; ZN = Ziehl-Neelsen.

Results were deemed to be valid if 100 or more plaques were observed on the RIF– plates, the positive control had 20–300 plaques and the negative control had 10 plaques or less.

A strain was considered to be susceptible to rifampicin if 10 plaques or less resulted from the rifampicin-containing sample (RIF+). This equated with the negative control cut-off value of 10 plaques. This demonstrated that no or very few viable mycobacteria were present.

A strain was considered to be rifampicin resistant if 50 or more plaques resulted from the rifampicin-containing sample (RIF+). This was indicative of viable TB bacilli surviving the rifampicin treatment.

An intermediate result was recorded when any strain produced between 11 and 49 plaques. Intermediate results may indicate emerging rifampicin resistance. Therefore a sample giving consistent intermediate results should be submitted for conventional susceptibility testing to confirm low grade resistance.

RESULTS

One hundred and ninety-one strains of *M. tuberculosis* isolated from sputum samples were used to compare the performance of the FASTPlaqueTB-RIF™ test with conventional tests. The results are summarised in Tables 1–4.

Of the 98 cultures tested at Laboratory 1, rifampicin susceptibility test results were available for both conventional methods for 94 strains (four strains failed to grow on Middlebrook 7H11 medium and were removed from further analysis). The comparison of FASTPlaqueTB-RIF™ with these results is shown in Tables 1 and 2. Of these, the Middlebrook 7H11 and

Table 1 Comparison of *FASTPlaqueTB-RIF*TM with Middlebrook 7H11 and Bactec rifampicin susceptibility test in 89 strains in which Bactec and Middlebrook 7H11 susceptibility results were in agreement (Laboratory 1)

<i>FASTPlaqueTB-RIF</i> TM	7H11 and Bactec method		Total
	Susceptible	Resistant	
Susceptible	60	0	60
Resistant	0	27	27
Intermediate	2	0	2
Total	62	27	89

Bactec 460 susceptibility results concurred in 89 of the strains tested (Table 1). For five strains, the results of the Middlebrook 7H11 and Bactec 460 susceptibility testing disagreed (Table 2). In each case, the Middlebrook 7H11 result showed the strain to be resistant to rifampicin, whereas the Bactec 460 result showed susceptibility. In each strain, the *FASTPlaqueTB-RIF*TM result agreed with the Middlebrook 7H11 result.

In Table 3, the *FASTPlaqueTB-RIF*TM results from 97 cultures tested at Laboratory 2 were compared with LJ susceptibility test results. *FASTPlaqueTB-RIF*TM correctly identified all the strains that were resistant, but reported two strains to be rifampicin-resistant that were susceptible by the proportion method. These two strains were re-tested by the *FASTPlaqueTB-RIF*TM method and were found to be susceptible to rifampicin.

The sensitivity, specificity and overall accuracy of *FASTPlaqueTB-RIF*TM were calculated by comparing the detection of resistant and susceptible strains with the gold standard proportion method, performed using Middlebrook 7H11 and LJ media, respectively (see Table 4).

DISCUSSION

This study evaluated the *FASTPlaqueTB-RIF*TM assay by comparing it to two different proportion methods and the Bactec 460 method, at two different sites. The sites were chosen to represent different susceptibility methods in routine use. The sensitivity, specificity and overall accuracy of the *FASTPlaqueTB-RIF*TM test were excellent. There was also agreement between the results obtained from studies performed at the two

Table 2 Comparison of *FASTPlaqueTB-RIF*TM with Middlebrook 7H11 rifampicin susceptibility test in five strains in which Bactec and Middlebrook 7H11 susceptibility results disagreed (Laboratory 1)

	Susceptibility test method		
	7H11	Bactec	<i>FASTPlaqueTB-RIF</i> TM
Isolate 1	Resistant	Susceptible	Resistant
Isolate 2	Resistant	Susceptible	Resistant
Isolate 3	Resistant	Susceptible	Resistant
Isolate 4	Resistant	Susceptible	Resistant
Isolate 5	Resistant	Susceptible	Resistant

Table 3 Comparison of *FASTPlaqueTB-RIF*TM with LJ rifampicin susceptibility test in 97 strains (Laboratory 2)

<i>FASTPlaqueTB-RIF</i> TM	LJ method		Total
	Susceptible	Resistant	
Susceptible	45	0	45
Resistant	2	49	51
Intermediate	1	0	1
Total	48	49	97

LJ = Löwenstein-Jensen.

different sites, suggesting that these results reflect the test's true performance in the field.

The results of the *FASTPlaqueTB-RIF*TM test were achieved more rapidly than the other methods tested (48 hours compared with 3–4 weeks for the 7H11 and LJ proportion methods, and 5–7 days for the Bactec method). Only rarely were intermediate results obtained with the *FASTPlaqueTB-RIF*TM test (3/191 or 1.5%). This compares favourably with the number (4/98 or 4%) of samples that could not be read due to poor growth on the medium in the samples analysed by the 7H11 proportion method.

In the five cases where the Bactec 460 radiometric method and the Middlebrook 7H11 method differed, the *FASTPlaqueTB-RIF*TM test agreed with the Middlebrook 7H11 result in each case. This is important, as the proportion method is the gold standard for susceptibility testing.³ The discrepancies are thought to be due to the slow growth of low numbers of drug-resistant organisms in the Bactec 460 system, although this could not be confirmed by an independent method (such as *rpoB* sequencing). Discrepancies between the Bactec 460 radiometric method and proportion methods have been previously reported in the literature and are not exclusive to this study.^{14,15}

Direct susceptibility methods using both the Middlebrook 7H10 (7H11) proportion method⁴ or the Bactec 460 radiometric method^{14–16} can be used to determine the susceptibility of *M. tuberculosis* directly from smear-positive decontaminated sputum. These methods can give results in 3–4 weeks and 7–21 days, respectively; however, they give a significant number of results that can not be interpreted due to bacterial

Table 4 Sensitivity, specificity and overall accuracy of *FASTPlaqueTB-RIF*TM at Laboratory 1 and 2 compared with indirect proportion methods

	Sensitivity *	Specificity †	Overall accuracy ‡
Laboratory 1 (<i>n</i> = 94)	1.00 (32/32) [§]	0.97 (60/62)	98% (92/94)
Laboratory 2 (<i>n</i> = 97)	1.00 (49/49)	0.94 (45/48)	97% (94/97)

* Sensitivity is the ability to detect true resistance.

† Specificity is the ability to detect true susceptibility.

‡ Overall accuracy is the number of correct results over the total number of results expressed as a percentage.

§ 27 strains were rifampicin-resistant by both 7H11 and Bactec methods. Five strains were resistant by the 7H11 method only.

contamination or insufficient growth of the control plates. Indirect testing must be used to confirm the results of these methods, and remains the only option available for determining the drug susceptibility of smear-negative patients. The use of a solid culture medium for primary isolation of *M. tuberculosis* together with *FASTPlaqueTB-RIF*TM for susceptibility testing would give results in a similar length of time compared with direct susceptibility testing using Middlebrook 7H11 medium from smear-positive sputum. Additionally, smear-negative specimens that are positive by culture can also be tested.

This study demonstrates that the performance of *FASTPlaqueTB-RIF*TM correlates very well with conventional rifampicin susceptibility test methods. Results are available within 48 hours from *M. tuberculosis* cultures, sooner than most current methods. This test offers the potential for rapid indication of *M. tuberculosis* strains that are likely to be multidrug-resistant, thus aiding patient treatment and reducing the spread of multidrug-resistant disease. No specialised equipment is required, giving the opportunity for its widespread application, particularly in low income countries.¹⁷

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RÉSUMÉ

CADRE : Deux laboratoires de référence en mycobactériologie : à Johannesburg (Laboratoire 1) et au Cap (Laboratoire 2), Afrique du Sud.

OBJECTIF : Déterminer la capacité du test *FAST-plaqueTB-RIF*TM à identifier correctement une sensibilité à la rifampicine dans les souches de *Mycobacterium tuberculosis* cultivées sur milieu solide.

SCHÉMA : Etude comparative de *FASTplaqueTB-RIF*TM et des méthodes conventionnelles de détection de la sen-

sibilité médicamenteuse avec des biais de sélection pour inclure un nombre suffisant de souches résistantes à la rifampicine.

RÉSULTATS : On dispose des résultats de la sensibilité à la rifampicine pour 191 souches de *M. tuberculosis*. Par les méthodes conventionnelles, on a décelé une résistance à la rifampicine dans 81 souches et une sensibilité dans 110 souches. La sensibilité, la spécificité et la précision globale de la technique *FASTplaqueTB-RIF*TM

ont été respectivement de 100%, 97% et 98% au Laboratoire 1 et de 100%, 94% et 97% au Laboratoire 2.

CONCLUSION : La performance de la *FASTplaqueTB-RIF*TM est comparable en matière de test de sensibilité à la rifampicine aux méthodes des proportions qui sont le «gold standard». Les nouvelles méthodes ont l'avantage

d'accélérer les résultats et ne nécessitent pas un équipement spécialisé. Dans ces conditions, la *FASTplaqueTB-RIF*TM peut être considérée comme un test rapide de résistance à la rifampicine susceptible d'une application très étendue.

RESUMEN

MARCO DE REFERENCIA : Dos laboratorios de referencia en Johannesburgo (Laboratorio 1) y Cape Town (Laboratorio 2), Sud África.

OBJETIVO : Determinar la capacidad del test *FAST-PlaqueTB-RIF*TM para identificar correctamente la sensibilidad de las cepas de cultivo de *Mycobacterium tuberculosis* en medio sólido.

MÉTODO : Estudio comparativo de *FASTPlaqueTB-RIF*TM y el método convencional de sensibilidad a las drogas, con un sesgo de selección que incluyera suficientes cepas resistentes a la rifampicina.

RESULTADOS : Se obtuvieron resultados de la sensibilidad a la rifampicina en 191 cepas de *M. tuberculosis*. Por los métodos convencionales se hallaron 81 cepas re-

sistentes a la rifampicina y 110 sensibles. La sensibilidad, especificidad y seguridad total para el *FAST-PlaqueTB-RIF*TM fueron respectivamente 100%, 97% y 98% en el Laboratorio 1 y 100%, 94% y 97% en el Laboratorio 2.

CONCLUSIÓN : El *FASTPlaqueTB-RIF*TM ofrece un resultado comparable a los métodos de las proporciones ('criterio estándar') para determinar la sensibilidad de la rifampicina ; el nuevo método tiene la ventaja de la mayor rapidez en los resultados, sin necesidad de equipos especializados. Esto hace del *FASTPlaqueTB-RIF*TM un test rápido, de amplia aplicación, para determinar la resistencia a la rifampicina.
