ABSTRACT

It has been recognized that management of the global TB problem can only be achieved with efficient and rapid diagnosis of the disease and the subsequent appropriate treatment of the patients. An innovative method, termed Phage Amplification Technology, uses bacteriophage to report the presence of viable mycobacterium tuberculosis (MTB) in a sample. Two products have been developed now by Biotic Laboratories Ltd, using this technology: FASTPlaque TB, which is a test for MTB detection and FASTPlaque TB-RIF for rifampicin susceptibility testing. In this study the performance of these technologies is compared with the results of conventional culture on Lowenstien Jensen (LJ) media and Mycobacterium Growth Indicator Tubes (MGIT). This study included; 50 tuberculous patients and 20 patients with chest disease other than tuberculosis served as control group (III).

Newly diagnosed tuberculous patients were classified into group I and II (each, 25 patients) of sputum Ziehl Neelsen (ZN) positive and ZN negative cases respectively. From group I and II, 25 patients were selected to perform rifampicin susceptibility testing served as group IV. Sputa were decontaminated, digested and concentrated by the standard NALC-NaOH treatment. From both groups I and II LJ slopes in duplicate were inoculated, culture on MGIT also was done. FASTPlaque TB test was performed for all patients. FASTPlaque TB RIF for rifampicin susceptibility in comparison with the results of MGIT susceptibility were done for group IV.

This study confirmed that the mean time of detection of MTB by FASTPlaque TB test is 2 days for the tuberculous patients (92% & 68% in group I and II respectively) with high significant difference in relation to the detection time by LJ medium (27.7± 3.8 days) in group I and in group II (30.9±5.8 days).

Meanwhile, the mean time of detection of MTB by MGIT was 7.5±1.9 days in 96% of group I and was 9.8±2.4 days in 76% of group II which is also higher than that of FASTPlaque TB test.

For group III (control group), no growth could be detected by LJ medium, MGIT and FASTPlaque TB test indicating 100% specificity.

For group IV, 15 cases (60%) were sensitive for rifampicin and 10 cases (40%) were resistant for rifampicin with 100% sensitivity and 100% specificity in comparison with the results of MGIT.

A combination of smear microscopy and FASTPlaque detected 80% of all TB positive specimens. FASTPlaque TB results were available within 48 hours from receiving the samples, so rapidly we can confirm TB in smear positive and to provide quick and certain diagnosis in smear negative TB.

FASTPlaque TB RIF test is a rapid and reliable bacteriophage based test to detect the rifampicin susceptibility within two days also.

The tests are easy to perform, require no specialized equipment, and rely on basic microbiological techniques.
INTRODUCTION

WHO estimated that about one-third of the world's population is infected with mycobacterium tuberculosis. There are about 8 millions new cases and about 3 millions deaths from TB annually\(^1\). The increasing HIV and the rise in multi drug resistant strains of TB (MDR-TB) exacerbates this problem\(^2\).

Diagnosis of TB is most often based upon both varieties of clinical signs, symptoms, and laboratory findings. These criteria are often insufficient to provide a clear diagnosis of TB. The classical methods for the diagnosis of pulmonary TB include smear microscopy which is rapid and accurate, but it is insensitive, it requires \(>10^4\) /ml organisms to give the results\(^3\). Also, it does not allow speciation of mycobacterium and hasn't the ability to detect both smear negative pulmonary TB and those with extra pulmonary TB\(^4\). Culture on LJ medium is specific, sensitive but it is slow. Recent cultures by Bactec systems are rapid but expensive, making them impractical to developing countries\(^5\).

Development of DNA probes and PCR assay now allow more sensitive and rapid diagnosis, but they are not always specific even in patients with smear positive and occasional false positive results do occur\(^6\).

Rifampicin resistance is a good predictor of MDR-TB in many parts of the world. Determination of rifampicin resistance will identify patients who will not respond to standard treatment regimens (at least 2 drugs, isoniazid and rifampicin)\(^7\).

Rapid diagnosis of TB and determination of rifampicin resistance are most useful from a clinical point of view to decrease the potential opportunity of spreading MDR-TB to the community\(^8\). Biotec laboratories developed a system for rapid detection and determination of drug susceptibility (48 hours) for MTB. FASTPlaque TB uses bacterial viruses to reflect the presence of target bacteria\(^9\).

FASTPlaque TB can play a valuable role in the diagnosis of TB and can assist in making a rapid and definitive diagnosis.

The Aim of the Study:

Any test that will be broadly accepted by the global TB diagnostic community needs to be cost effective, accurate, simple to perform, and easy to implement within the current infrastructure\(^10\). This study aims to evaluate the usefulness of the FASTPlaque TB (FPTB) assay for the rapid and specific detection of MTB in sputum. Also it aims to evaluate FPTB Rif as a manual test for rapid determination of the rifampicin susceptibility. Evaluation was based on comparison of this new technique with MGIT and LJ cultures which were used as gold standard.

PATIENTS AND METHODS

Patients:

Seventy patients were selected from chest department of Benha University Hospital during the period from January-June 2002. They were classified into: 25 patients of ZN sputum +ve, active pulmonary TB (group I), 25 patients of sputum smear-ve TB (group II) and 20 patients with chest diseases other than TB as a control group e.g. pneumonia (7 cases), bronchiectasis (7 cases) and chronic bronchitis (6 cases) (group III).

Group IV (25 patients) was selected from group I (15 patients) and group II (10 patients), they were subjected to Rifampicin susceptibility test.

To all patients the following were done:

History taking, complete blood picture, erythrocyte sedimentation rate, liver and kidney function tests, plain x-ray chest postero-anterior and lateral views, sputum for acid fast bacilli (AFB) by ZN stain, sputum culture on LJ, FASTPlaque TB test and on MGIT. Drug susceptibility by FASTPlaque TB Rif TM and by MGIT tests also was done. The results were tabulated and statistically analyzed.

Methods:

Specimens processing:

Morning sputa (3 days) were subjected to decontamination, liquefaction and concentration by using N-Acetyl-L-Cysteine-NaOH 4% (NALC) method\(^11\), to inhibit growth of faster growing bacteria or fungi\(^12\). Sputum was centrifuged with equal volume of NALC-NaOH

FASTPlaque TB (Soheir A.R. et al.)
solution, and then mixed until liquefied.

Sterile Phosphate Buffer Solution to reach pH 6.8 was used. The tubes were centrifuged for 15 minutes at 2000 g to concentrate the specimen (13, 14).

1. Ziehl-Neelsen staining (ZN) (15):

   The processed sputum was stained for AFB, the results were reported according to American Thoracic Society (16).

2. Culture of Mycobacterium tuberculosis:

   A) Procedure of culture on LJ: For each processed specimen, two bottles of Bacto-Lowenstein Jensen medium were inoculated, incubated at 37°C in a horizontal position for 24 hours to ensure even distribution of the inoculums. After that incubation was continued in an upright position for 6-8 weeks. Meanwhile, the bottles were inspected for growth at regular intervals, to detect rapid growers, to remove contaminated cultures, and to detect characteristic morphological TB colonies. Smear was examined to ensure acid fast bacilli (17).

   B) Culture on FASTPlaque TB™ (Biotic Laboratories Ltd UK):

   Principle of FASTPlaque TB™:-

   It utilizes mycobacteriophage (viruses that specifically infect or target mycobacteria) to reflect the presence of viable MTB. The target bacterial cells in the treated specimens are rapidly infected by the specific bacteriophage (Actiphage™). The resulting mixture is then treated with a virucidal solution (Virusol™) for destruction of all bacteriophage which have not infected host cells.

   The only bacteriophage that remain, (protected within viable target mycobacteria) continue to replicate until new progeny are released as the cells lyses. These progeny are then amplified by the introduction of a non-pathogenic rapid growing cell host (Sensor™ cells). Lyses is seen as clear areas (plaques) in a lawn of confluent growth of Sensor™ cells. The number of plaques generated from a given sample is related to the number of viable MTB. If there are no viable MTB in the original sample, there will be no bacteriophage to detect as plaques at the end (18, 19 & 20). All materials were provided with the kit. The steps of the assay were done according to the manufacturer's instructions.

   Interpretation:

   Negative control is at < 10 plaques, but positive control is at 20-300 plaques, for decontaminated sputum. 0-19 plaques indicate negative but ≥20 plaques is Positive FASTPlaque TB™.

   C) MGIT Culture (Becton Dickinson Microbiology systems company - USA):

   The fluorescent compound embedded in the bottom of the tubes is sensitive to the presence of oxygen dissolved. Large amount of oxygen quenches the emissions from the compound and fluorescence can be detected. Decontaminated concentrated sputum suspension (0.5 ml) was used, volumes greater than 0.5 ml can increase contamination or change the performance of the tubes. The tubes were incubated at 37°C. The positive and negative control tubes for the interpretation of fluorescence were used. Tubes were read daily starting on the second day, then twice weekly for the last 4 weeks. Positive tubes should be stained for AFB. Smear-ve tubes should be checked for bacterial contamination. Steps of the assay were according to the manufacturer's instructions.

3. Drug Susceptibility Test:

   A) Using FASTPlaque TB-RIF™, (Biotic Laboratories Ltd UK)

   It is a bacteriophage-based test for determination of rifampicin susceptibility of MTB cultures within 48 hours on the bases of FASTPlaque™ principle (18). The number of plaques in a rifampicin-free (RIF-) is compared with the number of plaques produced from a sample incubated in the presence of rifampicin (RIF+). The absence of plaques in the rifampicin-containing sample indicates that TB bacilli are susceptible (i.e. they are no longer viable and can not support phage replication). The presence of plaques in the rifampicin-containing sample indicates that viable TB bacilli have survived and the strain is resistant to rifampicin.

   The FASTPlaque TB-RIF™ Susceptibility Test has been used a fresh mycobacterium culture (from LJ up to 3 weeks old), older cultures may give inaccurate results. Test suspension from culture was done according to manufacturers instructions (all materials were provided by the kit). 0.5 ml of this suspension was added to 10 UG/ml rifampicin solution (RIF+) and to 0.5ml FPTB medium in a sterile glass bottle containing 6-8 glass beads. Then it was mixed and incubated for 24 hours at 37°C. Infect with Actiphage for 90 minutes then virucide was added and incubated 5 min, neutralization with 5ml FATB Plus and 1 ml of sensor cells were added. 5ml molten FPTB agar was used with the above mixture. Positive and negative Controls were prepared. The entire contents of the reaction vessel were poured into the Petri dish. The agar was allowed to set; each dish was inverted and incubated overnight at 37°C.
Interpretation:

Positive control has 20-300 plaques, whereas negative control if 10 plaques or less was detected. For isolates giving < 100 plaques on the RIF -ve plate, the test must be repeated. If RIF +ve plate has 50 plaques or greater, the isolate was resistant. If RIF +ve plate has 10 plaques or less the isolate was susceptible.

B) MGIT anti-microbial susceptibility test:

The specimen of positive AFB in MGITs was adjusted to a 1.0 McFarland. For each sample the rifampicin containing MGIT tube and one control tube without drug were inoculated and incubated at 37°C and then examined for fluorescence at 365nm UV. The results were interpreted only after the growth control tube was fluoresced.

A test result was considered resistance, if the drug-containing tube fluoresced within 2 days of the time that the growth control tube fluoresced. A result was considered susceptible if the drug-containing tube did not fluoresce in 2 days of the time of control tube to fluoresce. The late emergence of drug-resistant mutants was controlled by reading MGIT for 6 weeks. The mean time fluorescence for the positive growth control was 5.5 days.

RESULTS

In this study, group I & II (each 25 patients) of newly diagnosed sputum smear positive and smear negative for AFB. Group III served as control group included 20 patients with chest diseases other than TB. From group I and group II, 25 patients were selected to perform rifampicin susceptibility test served as group IV. Each group involved 16 male and 9 female. All patients were selected at the same age, so no statistical differences were detected.

All samples of group I could grow and be isolated on LJ media, 23 gave positive results with FASTPlaque TB and 24 gave positive growth by MGIT. The mean time of isolation was 27.7 days ±3.8 by LJ, and it was 2 days by FASTPlaque. By MGIT the mean time of isolation was 7.5 days ±1.9 (Tables 1 and 2).

There were 5 cases of smear negative (group II) showing no growth on all the 3 used methods. Twenty cases revealed growth on LJ, the mean time of isolation was 30.9 days ±5.8. While 19 cases gave positive results with MGIT and the mean time of isolation was 9.8 days ±2.4. Seventeen cases gave positive results with FASTPlaque TB, the mean time of isolation was 2 days (Tables 1 & 3).

The number of plaques for group I, group II and control group (III) are seen in table 4. Table 5 shows the radiological extent in patients in groups I & II. Tables 6 & 7 show the relation between growth of FAST-TB and both LJ and MGITs.

Rifampicin susceptibility tests were done by both FASTPlaque T.B. RifTMT test and MGIT test. These results were seen in table (9).

Table 1: The detection rate by different used methods.

<table>
<thead>
<tr>
<th>Group I</th>
<th>LJ</th>
<th>MGIT</th>
<th>FAST Plaque</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group I smear +ve</td>
<td>No %</td>
<td>No %</td>
<td>No %</td>
</tr>
<tr>
<td>Group I smear -ve</td>
<td>25 100</td>
<td>24 96</td>
<td>23 92</td>
</tr>
<tr>
<td>Total</td>
<td>45 90</td>
<td>43 86</td>
<td>40 80</td>
</tr>
</tbody>
</table>

Table 2: Time in days of isolation of smear +ve (group I)

<table>
<thead>
<tr>
<th>Group I</th>
<th>LJ</th>
<th>FPTB</th>
<th>MGIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Range</td>
<td>22-35</td>
<td>2</td>
<td>3-9</td>
</tr>
<tr>
<td>Mean</td>
<td>27.7</td>
<td>7.5</td>
<td>±1.9</td>
</tr>
<tr>
<td>S.D. ±</td>
<td>±3.8</td>
<td>0</td>
<td>±.5</td>
</tr>
<tr>
<td>S.E. ±</td>
<td>±.9</td>
<td>0</td>
<td>18.87</td>
</tr>
<tr>
<td>t-test</td>
<td>25.79</td>
<td>&lt;0.001</td>
<td></td>
</tr>
</tbody>
</table>

Key: Lowenstein Jensen: LJ    FASTPlaque TB: FPTB    MGIT: Mycobacterial Growth Indicator Tube
P-value < 0.005 indicates highly significant and >0.05 is considered insignificant. P1-value reflects the significance between LJ and FASTPlaque. P2-value reflects the significance between LJ and MGIT.

FASTPlaque TB (Soheir A.R. et al.)
Table (3): Time in days of isolation of sputum -ve (group II)

<table>
<thead>
<tr>
<th>Group</th>
<th>F.P.TB</th>
<th>MGIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Range</td>
<td>27-48</td>
<td>4-10</td>
</tr>
<tr>
<td>Mean</td>
<td>2</td>
<td>9.8</td>
</tr>
<tr>
<td>S.D.±</td>
<td>± 5.8</td>
<td>± 2.4</td>
</tr>
<tr>
<td>S.E. ±</td>
<td>±1.78</td>
<td>±0.68</td>
</tr>
<tr>
<td>t-test</td>
<td>15.538</td>
<td>12.01</td>
</tr>
</tbody>
</table>

P1-value < 0.001
P2-value < 0.001

Key 2: it is the same as key 1

Fig. (A): A positive case of FASTPlaque.

Fig. (B): A negative case of FASTPlaque.

Table (4): Number of plaques in tuberculous and non-tuberculous groups

<table>
<thead>
<tr>
<th>Group</th>
<th>Plaques</th>
<th>&lt;20</th>
<th>20-300</th>
<th>&gt;300</th>
<th>No. of pts.</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>0</td>
<td>10</td>
<td>15</td>
<td></td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>8</td>
<td>7</td>
<td>10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>20</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table (5): Radiological extent in patients of both group I and II.

<table>
<thead>
<tr>
<th>Group</th>
<th>Minimal</th>
<th>Moderate</th>
<th>Far advanced</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group(I) smear +ve</td>
<td>10</td>
<td>20</td>
<td>7</td>
</tr>
<tr>
<td>Group(II) smear -ve</td>
<td>9</td>
<td>18</td>
<td>9</td>
</tr>
<tr>
<td>Total</td>
<td>19</td>
<td>38</td>
<td>16</td>
</tr>
</tbody>
</table>

Table (6): Total positive and negative cultures by LJ and Fastplaque.

<table>
<thead>
<tr>
<th></th>
<th>LJ +ve</th>
<th>LJ -ve</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fastplaque +ve</td>
<td>40</td>
<td>0</td>
<td>40</td>
</tr>
<tr>
<td>Fastplaque -ve</td>
<td>5</td>
<td>5</td>
<td>10</td>
</tr>
<tr>
<td>Total</td>
<td>45</td>
<td>5</td>
<td>50</td>
</tr>
</tbody>
</table>

Table (7): Total Positive and negative cultures by LJ and MGIT.

<table>
<thead>
<tr>
<th></th>
<th>LJ +ve</th>
<th>LJ -ve</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>MGIT +ve</td>
<td>43</td>
<td>0</td>
<td>43</td>
</tr>
<tr>
<td>MGIT -ve</td>
<td>2</td>
<td>5</td>
<td>7</td>
</tr>
<tr>
<td>Total</td>
<td>45</td>
<td>5</td>
<td>50</td>
</tr>
</tbody>
</table>

Table (8): Over all sensitivity and specificity of detected methods.

<table>
<thead>
<tr>
<th></th>
<th>LJ</th>
<th>Fastplaque</th>
<th>MGIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>95%</td>
<td>95%</td>
<td>98%</td>
</tr>
<tr>
<td>Specificity</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

Table (9): Rifampicin susceptibility by both FASTPlaque and MGIT

<table>
<thead>
<tr>
<th></th>
<th>FASTPlaque</th>
<th>MGIT Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitive</td>
<td>16 (60%)</td>
<td>16 (60%)</td>
</tr>
<tr>
<td>Resistant</td>
<td>9 (40%)</td>
<td>9 (40%)</td>
</tr>
</tbody>
</table>

**DISCUSSION**

Microscopy does not, by definition, detect cases of ZN smear-negative (low number of bacilli) pulmonary TB. It also does not detect most cases of extra-pulmonary TB (21). When AFB microscopy is the mean to diagnose the disease, approximately 1/3-2/3 of all
cases of TB remain undiagnosed. The sensitivity of diagnosis is increased by sputum culture, either on solid or selective liquid media (22). Sputum culture on solid media is not technically difficult but it requires several weeks before the results can be seen.

Rapid diagnosis for MBT is needed for both patients and communities, so effective treatment benefits communities by limiting the spread of the disease. New products are urgently needed for the diagnosis of TB, FASTPlaque TB™, a new rapid test for the diagnosis of TB, was launched in the year 2000 by BioLec Laboratories Ltd.

In the present study, all groups were age matched with no statistical differences. All cases of group III gave negative growth by the used methods, so these methods are 100% specific for detection of AFB.

The results showed that all cases of group I could grow on LJ media, with 100% sensitivity and specificity. 23 (92%) positive cases were detected by FASTPlaque TB. and 24 (96%) samples were positive by MGIT. The mean time of isolation was 27.7 days ±3.8 by LJ media, and it was 2 days by FASTPlaque. By MGIT culture the mean time of isolation was 7.5 days ±1.9.

The statistical analysis of these results showed highly significant difference (P-value <0.001) between the time of detection by LJ and that by FASTPlaque TB test and also between LJ and MGIT.

Levidioton et al. (1999) (23) in Greece reported that, MGIT system had 98.7% sensitivity and 100% specificity, with a mean time of detection was 8 days, but LJ had mean time of detection 30 days. While Ardito et al. (2000) (24) in Italy reported that MGIT had 100% sensitivity and the main time of detection was 10 days for MGIT and 25 days for LJ.

Muzaffar et al. (2001) (25), studied 199 smear positive cases, 142 cases were positive by FASTPlaque TB out of 160 positive cases by LJ, so the sensitivity was 89%. The results obtained in the current study were compared to the results (86.8 %) by Albert et al. (2001 A) (26), which were confirmed by another study done after one year by Albert et al. (2002 A) (27). The difference of our results and these studies may be due to the large samples of others. Our results were higher than some results of a study by Muzaffar et al. (2002 A) (28), which was done in several locations in Asia, Africa and Europe in which the sensitivity ranged from 65% to 83%.

As regards sputum ZN negative cases (group II), there were 20 cases gave growth on LJ with the mean time of isolation 30.9 days ± 5.8. Out of them, 19 (76%) gave positive results by MGIT with mean time of isolation of 9.8 days ±2.4. Seventeen cases (68%) gave highly positive results by FASTPlaque TB with the mean time of isolation of 2 days.

The statistical analysis of detection time showed highly significant difference between that of LJ and FASTPlaque and also between LJ and MGIT (P-value <0.001).

There are several reasons for the occurrence of false negative results, FASTPlaque TB requires active, viable bacilli and intact phage receptors on the cell surface to allow phage attachment and replication. Expression of phage receptors and efficiency of phage replication may vary depending on the strain of TB or the physiological state of the bacilli (Albert et al., 2002A) (27).

From the results of our study, the sensitivity of FASTPlaque TB test to detect the tubercle bacilli in ZN negative sputum was 85% of the growth on LJ (17-20).

Muzaffar et al. (2001) (25), studied 326 smear negative cases, 44 cases were positive by FASTPlaque TB test out of 65 positive cases by LJ, so the sensitivity was 68%. But by Albert et al. (2001 A) (26), the sensitivity was 48.8% and it was 55% in another study done by Albert et al. (2001B) (29), which was different from our results. These results were also different from that obtained (48.7%) by Albert et al. (2002 A) (27).

In our work the number of plaques for ZN positive (group I) was >20 plaques in 8 cases, >300 plaques in 15 cases and <19 in 2 cases. The number of plaques
>20 indicate positive result i.e. there were viable tubercle bacilli. Plaques >300 indicates complete lyses which was considered highly positive.

The number of plaques for smear negative cases (group II) were >20 plaques in 7 cases, >300 plaques in 10 cases and <19 plaques in 8 cases.

The number of plaques for control (group III) was ranging from 0-9 plaques. This means that all were negative for tuberculosis. So, the specificity of FASTPlaque TB test is 100%.

These results were almost in agreement with Albert, et al. (2001A) (26), who studied 781 clinical samples (sputum). He obtained positive results with 78 samples of 111 true tuberculosis and 7 samples gave false positive results of 670 true non-tuberculosis samples. The specificity was 99%, which is nearly equal to that of ours. Also it was in agreement (99%) with that obtained by Albert et al. (2001B) (29), Muzaffar et al. (2002B) (30), and Albert et al. (2002A) (27).

In contrast, Muzaffar et al. (2001) (25) reported the specificity was 97%. The difference between our results versus mentioned studies may be due to the large number of cases used in them.

As FASTPlaque TB results were available within 48 hours, the test can be used to rapidly confirm TB in smear positive cases and to provide certain diagnosis in smear negative TB.

The high specificity leads to a very low incidence of false positive results. This means that a positive result from FASTPlaque TB can be used as a good indicator of the presence of active TB disease, and that very rarely will TB treatment be initiated unnecessarily.

Rifampicin resistance is a good predictor for MDR tuberculosis. The assays for its detection are appropriate for widespread application in the fight against tuberculosis and MDR-TB in both the developing and the industrialized world, conventional testing takes 3-4 week to detect anti TB susceptibility (Albert et al., 2001C) (31).

Our results of rifampicin susceptibility on patients of group IV by FASTPlaque showed that, the number of plaques in 15 (60%) cases sensitive for rifampicin was <20 plaques and in the 10 cases resistant for rifampicin was >50 plaques.

Assessment of the rifampicin susceptibility by both FASTPlaque TB RIF/FM test and MGIT test showed that 15 cases that were sensitive for rifampicin by FASTPlaque TB RIF/FM test were also sensitive by MGIT test. Ten cases that resistant for rifampicin by FASTPlaque TB RIF/FM test were also resistant by MGIT test. The sensitivity of FASTPlaque T.B. RIF/FM test to detect rifampicin resistant cases was 100% (10/10). This result was in agreement with Trollip, et al. (2001A) (10), (42/42), Padayachee, et al. (2002) (32), (11/11) and Anandhi et al. (2002) (33) (42/42). Also it was in agreement with Trollip et al. (2001B) (34) (32/32), Albert et al. (2001C) (31) and Albert et al (2002B) (35), in which the sensitivity was 100% in all studies. It was different from the result obtained by Adiguzel et al (2002) (36), in which the sensitivity was 81.57%.

The specificity of FASTPlaque T.B.RIF/FM test to detect rifampicin sensitive cases was also 100%. It was nearly equal to the result obtained by Trollip, et al, (2001A) (10) (99%), Trollip et al. (2001B) (34) (97%), Anandhi et al. (2002) (33) (98.8%) and Albert et al. (2002B) (35) (99%) but different from that obtained by Padayachee et al. (2002) (32) (73%) and Adiguzel et al. (2002) (36), (30%).

In this study, the percent of rifampicin sensitivity and initial resistance among group IV by both FASTPlaque TBRIF and MGIT were the same: 60% sensitive and 40% resistant. We can observe that FASTPlaque TB rif. test is the most rapid, it needs only 48 hours to give the results, while MGIT needs 5-8 days.

It was concluded that LI had the highest sensitivity (90%) and specificity (100%) followed by MGIT test with sensitivity 86% and specificity 100%. The last was that of FASTPlaque TB test with sensitivity 80% and specificity 100%. On the other hand FASTPlaque TB method is the most rapid one (only 2 days). So
FASTPlaque TB method is essential for the rapid diagnosis of tuberculosis, this is of particular value in smear negative cases for limitation of the spread of the infection in the community. It is also simple to perform less expensive and none hazardous to use in labs in developing countries without the requirement for expensive instrumentation.

We hope to achieve developments in the future to diagnose TB in children and from extra-pulmonary samples also to detect rifampicin in resistance directly from sputum in 2 days.

**Reference**


FASTPlaque TB (Soheir A.R. et al.)


