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# Evaluation of *FASTPlaque*TB™ to diagnose smear-negative tuberculosis in a peripheral clinic in Kenya

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**SUMMARY**

**OBJECTIVE: To evaluate the performance and feasibility of *FASTPlaque*TB™ in smear-negative tuberculosis (TB) suspects in a peripheral clinic after laboratory upgrading.**

**DESIGN: Patients with cough ⩾2 weeks, two sputum smear-negative results, no response to 1 week of amoxicillin and abnormal chest X-ray were defined as smear-negative suspects. One sputum sample was collected, decontaminated and divided into two: half was tested with *FASTPlaque*TB in the clinic laboratory and the other half was cultured on Löwenstein-Jensen medium in the Kenyan Medical Research Institute. Test sensitivity and specificity were evaluated in all patients and in human immunodeficiency virus (HIV) infected patients. Feasibility was assessed by the contamination rate and the resources required to upgrade the laboratory.**

**RESULTS: Of 208 patients included in the study, 56.2% were HIV-infected. Of 203 *FASTPlaque*TB tests, 95 (46.8%) were contaminated, which interfered with result interpretation and led to the interruption of the study. Sensitivity and specificity were respectively 31.2% (95%CI 12.1–58.5) and 94.9% (95%CI 86.8–98.4) in all patients and 33.3% (95%CI 9.9–65.1) and 93.9% (95%CI 83.1–98.7) in HIV-infected patients. Upgrading the laboratory cost €20 000.**

**CONCLUSION: *FASTPlaque*TB did not perform satisfactorily in this setting. If contamination can be reduced, in addition to laboratory upgrading, its introduction in peripheral clinics would require further assessment in smear-negative and HIV co-infected patients and test adaptation for friendlier use.**

**KEY WORDS:** tuberculosis; phage-based test; smear microscopy; diagnosis; developing countries

IN COUNTRIES with limited laboratory capacity, the diagnosis of pulmonary tuberculosis (TB) is based on direct sputum smear microscopy following World Health Organization (WHO) and International Union Against Tuberculosis and Lung Disease (The Union) guidelines.[1,2] Microscopy is inexpensive, but it has low sensitivity, particularly in human immunodeficiency virus (HIV) co-infected patients.[3] This is unfortunately the only bacteriological test available in peripheral health clinics in resource-poor countries, where the majority of patients seek care. More sensitive methods, such as *Mycobacterium tuberculosis* culture, are only available in referral laboratories. Diagnosis of smear-negative TB patients is empirically based on the use of algorithms that consider radiological signs and response to antibiotic treatment. The performance of algorithms in HIV-infected patients is poor,[4,5] resulting in delayed treatment, compromised prognosis and prolonged TB transmission.[6]

Although several promising diagnostic tests are in the development pipeline, few are likely to be suitable for microscopy laboratories in the short to medium term.[7,8] *FASTPlaque*TB™ (Biotec Laboratory Ltd, Ipswich, UK), a test based on the use of mycobacteriophages to reflect the presence of viable *M. tuberculosis* in sputum specimens (detection threshold of about 100 bacilli), was identified as a potential alternative for diagnosing smear-negative TB.[9] According to the manufacturer, this test can deliver results within 48 h and is relatively cheap (€2.50/test). Some studies have reported a sensitivity of between 50% and 75% and a specificity of 98% in smear-negative TB suspects.[10,11] The authors suggest a role for this test in the early diagnosis of clinically suspected smear-negative cases.[12,13] Evaluations to date have been conducted only in university or reference laboratories.[9]

Given the lack of appropriate diagnostics for use in basic laboratories, we upgraded a peripheral laboratory to make it more appropriate for more advanced testing, and conducted a prospective field evaluation of the performance and feasibility of *FASTPlaque*TB to diagnose smear-negative TB patients under operational conditions.

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## METHODS

### *Participants*

Study participants were recruited in an urban out-patient clinic supported by the Kenyan Ministry of Health and Médecins Sans Frontières (MSF), which provides HIV and TB care to the community living in the slum of Mathare, Nairobi City, Kenya. In 2001, the HIV prevalence in the adult population of Nairobi was estimated at 15%, while 50% of TB patients were HIV co-infected.[14] Consecutive patients aged >15 years with cough >2 weeks were screened with sputum smear microscopy. Only those defined as smear-negative pulmonary TB suspects based on the combination of two Ziehl-Neelsen (ZN) smear-negative results, no clinical response to a 1-week trial of amoxicillin and abnormal chest X-ray (CXR) were eligible for the study.[15] A suggestive CXR was defined as the presence of pleural effusion, lymphadenopathy, cavity or miliary.[15] Exclusion criteria were intake of anti-tuberculosis drugs or quinolones in the 4 weeks before screening and episodes of moderate to severe haemoptysis (⩾50 ml) in the last 7 days. Demographic information, treatment history and clinical characteristics were recorded through patient interview. Pre- and post-HIV test counselling was offered to all those patients included in the study. Free HIV care was available, including antiretroviral treatment if indicated, based on CD4 cell count.

Approval for the study was provided by the National Ethical Review Committee of the Kenyan Research Institute (KEMRI, Nairobi, Kenya) and the Comité de Protection des Personnes (Ile-de-France XI, France). Written informed consent was obtained from each subject.

### *Laboratory methods*

*M. tuberculosis* culture on Löwenstein-Jensen (LJ) medium was used as the reference standard for this evaluation, and was performed in the KEMRI Mycobacteriology Laboratory. Eligible patients were required to produce a minimum of 1 ml sputum on the spot in a 50 ml sterile conical tube after clear instructions had been given on how to produce a good quality specimen. To prevent the risk of nosocomial transmission, specimens were collected outdoors. Macroscopic appearance of the specimen was recorded as 'purulent', 'mucopurulent', 'mucoid', 'blood-stained' or 'salivary'.

The *FASTPlaque*TB kit consists of eight tests and one positive and one negative control. *FASTPlaque*TB requires 3 days from specimen collection to availability of results: the first day for the specimen preparation, the second day for assay procedure and the third day for interpreting the results. Specimens for *FASTPlaque*TB were processed in accordance with the manufacturers' instructions, available on the Biotec website,* except in relation to batching of the specimens: due to the small number of eligible patients per day, we adapted the manufacturer's guidelines and processed the specimens once a week to reduce waste of reagents. Non-decontaminated specimens were therefore refrigerated at 4°C until use, and were then decontaminated, cultured and processed with *FASTPlaque*TB on the same day. The entire specimen was decontaminated using *N*-acetyl-L-cysteine/sodium hydroxide *N*-acetil-L-cysteine/sodium hydroxide, followed by neutralisation with phosphate buffer. For the purpose of the study, half of the specimen was transferred with a sterile pipette to a sterile 50 ml conical centrifuge tube to be processed with *FASTPlaque*TB, and the remaining portion was labelled and sent the same day to the KEMRI laboratory for culture.

The assay procedure started with the mixture of the decontaminated specimen with the *FASTPlaque*TB Medium Plus reagent followed by centrifugation. One ml of the suspension was then transferred to a labelled reaction vessel and incubated at 37°C overnight to enrich viable TB bacilli present in the sample. On day 2, after enrichment, 0.1 ml of the mycobacteriophage solution was added and incubated for 1 h; 0.1 ml of virucide solution was then added to destroy all bacteriophages that had not infected host cells, and incubated at room temperature for 5 min; 5 ml *FASTPlaque*TB Medium Plus was then added to neutralised excess virucide, followed by 1 ml of sensor cells. The contents of the vessel were added to a sterile Petri dish and overlayered with 5 ml molten agar. The plates were rotated several times, clockwise and counterclockwise, after pouring. These were then allowed to set, and were incubated at 37°C overnight. The next day, the number of plaques was counted following the manufacturer's recommendations. A cut-off of 20 plaques was used to define a positive result. The fusion of plaques giving the aspect of confluent or complete lysis of the lawn of cell growth also defined a positive result. Based on the manufacturer's guidelines, contamination was defined as 'contamination that interferes with interpretation' when the growth of contaminating bacteria obscured the lawn of Sensor cell growth and did not allow the interpretation of the plate, or 'contamination that does not interfere with interpretation' when contaminating bacteria were present as discrete colonies on the lawn. Safety measures similar to those required to set up *M. tuberculosis* culture were followed to process the test, as recommended by the manufacturer, and safety guidelines were introduced for disposal of pathogenic biological waste and in case of laboratory accidents.

At KEMRI, the specimens were centrifuged and the deposits cultured on LJ media and incubated at 37°C for up to 8 weeks. The slants were inspected weekly. All positive cultures (based on the WHO culture grading scale) were confirmed for presence of acid-fast bacilli by ZN microscopy, and strain identification was done using temperature growth range,

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pigment production, resistance to *p*-nitrobenzoic acid (500 mg/l) and thioxyphene carboxylic acid hydrazide (2 mg/l) and niacin production.[16,17]

For HIV testing, UniGold (Trinity Biotech, Bray, Ireland) and DETERMINE (Inverness Medical, Waltham, MA, USA) tests were performed simultaneously; the CAPILLUS test (Cambridge Diagnostics, Galway, Ireland) was used in case of discordant results.

Inter- and intra-reader reproducibility was assessed by the reading of random selections of plates a second time on the same day by a different technician, and by the same technician 24 h after the first reading, respectively. The laboratory supervisor masked the plate identification to ensure blind reading. All plates were refrigerated at +4°C for 24 h. In addition to this assessment, the study laboratory supervisor reread a sample of plates blind within 24 h for internal quality control.

A list of parameters was measured to evaluate the operational aspects of the test: duration of 1) weekly sterilisation of containers and 2) weekly preparation of reagent; 3) specimen preparation (day 1 of the specimen processing); 4) *FASTPlaque*TB assay procedure (day 2); and 5) the reading of the plates (day 3). The cost of the test and the consumables needed to perform *FASTPlaque*TB was assessed based on the Kenyan market price and within the context of a study.

To perform *FASTPlaque*TB, an additional room was allocated to the one-roomed microscopy laboratory of the health clinic and renovated to create the necessary aseptic conditions; a microbiological safety cabinet and other requisite equipment were installed (centrifuge, incubator, hotplate and automatic pipette); electrical power back-up was installed to ensure uninterrupted overnight incubation; and two smear microscopy technicians were trained for 2 months in aseptic techniques and in the assay procedure.

### *Statistical methods*

Sample size was calculated using an expected sensitivity of *FASTPlaque*TB against *M. tuberculosis* culture of 50% in smear-negative pulmonary TB suspects, 10% precision and a risk $\alpha$ of 0.05.[9,10] To assert this hypothesis, 97 patients positive for *M. tuberculosis* culture were required. With an estimation of 25% culture positivity among smear-negative suspects and a 15% increase to cover potential dropouts, 450 smear-negative suspects were required to evaluate the accuracy of the test.

Data were double entered using Epidata 3.1 (EpiData Association, Odense, Denmark) and analysed using SPSS® 11.0 for Windows (SPSS Inc, Chicago, IL, USA). Simple proportions and means were calculated to present patient and specimen characteristics. The $\chi^2$ test was used to compare proportion, with $P$ value $<0.05$ to ascertain significance. Sensitivity, specificity, predictive values and likelihood ratios were calculated to measure the performance of the test in all cases and in the subgroup of HIV-infected cases. Positive likelihood ratio above 10 and negative likelihood ratio below 0.1 were considered to provide strong evidence for rule in or rule out diagnoses.[18] Inter- and intra-reader reproducibility was assessed by the calculation of the kappa ($\kappa$) coefficient, which measures the agreement between the two readings. A $\kappa$ between 0.80 and 1 signified an almost perfect agreement.[19] A 95% confidence interval (CI) was used to quantify uncertainty.

## RESULTS

A total of 970 patients with cough for >2 weeks were screened between May 2005 and June 2006. Of these, 208 were smear-negative pulmonary TB suspects (Figure 1). The characteristics of all patients and the subgroup of HIV-infected patients are presented in Tables 1 and 2. Of the 152 patients who accepted HIV testing, 117 were HIV-infected (76.9%). Of the 208 patients included and the 117 HIV-infected patients, respectively 114 (54.8%) and 67 (57.3%) had a CXR suggestive of TB.[17]

Of the 208 collected specimens, 161 were purulent (77.4%), 42 mucoid (20.2%) and five bloodstained (2.4%). *M. tuberculosis* culture was performed in 205 patients (98.6%), of whom 32 (15.6%) had positive results, 163 (79.5%) had negative results and 10 (4.9%) were contaminated. After exclusion of the contaminated cultures, 32/195 (16.4%) patients were *M. tuberculosis* culture-confirmed. *FASTPlaque*TB assay procedure failed in five patients (no addition of Sensor cell and absence of media set), which resulted in

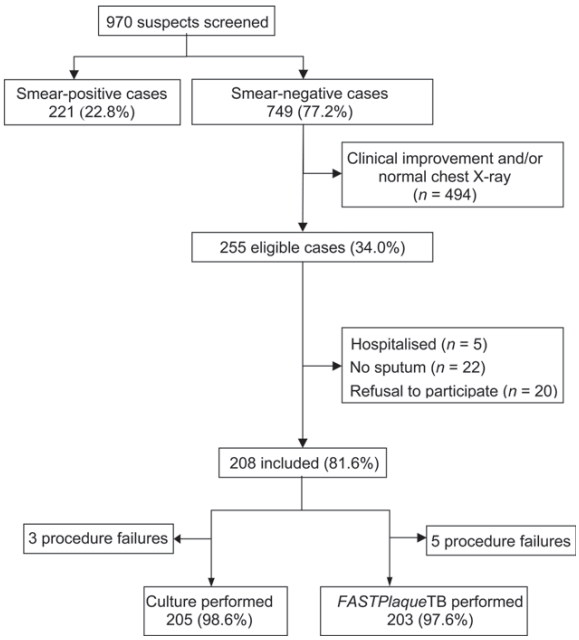


**Figure 1** Study profile.

**Table 1** Demographic characteristics, TB treatment history and HIV status of included patients

| | Results |
|---|---|
| VCT, *n*/*N* (%) | |
| Positive | 117/208 (56.2) |
| Negative | 35/208 (16.8) |
| Refused testing | 56/208 (27.9) |
| Sex ratio (male/female) | |
| Overall | 0.5 (74/134) |
| HIV-positive | 0.4 (31/86) |
| Age, mean (SD) | |
| Overall | 34.5 (10.4) |
| HIV-positive | 34.9 (8.5) |
| Past TB history, *n*/*N* (%) | |
| Overall | 60/208 (28.8) |
| HIV-positive | 40/117 (34.2) |

TB = tuberculosis; HIV = human immunodeficiency virus; VCT = voluntary counselling and training; SD = standard deviation.

available tests for 203 patients (97.6%). Among the 203 plates, 95 (46.8%) presented contamination that interfered with interpretation and 71 (35.0%) that did not interfere with interpretation, giving an overall plate contamination rate of 81.8% (Figure 2). The *FASTPlaque*TB result was negative in 98 (48.3%) cases and positive in 10 (4.9%). Table 3 presents the *FASTPlaque*TB results according to the culture results.

The unexpectedly high rate of unreadable tests due to plate contamination was reported to the study's scientific advisory board, which recommended that patient recruitment be discontinued in June 2006, before the planned sample size was reached.

The cause of contamination was investigated. The most common contaminant was an aerobic gram-positive spore-forming bacillus. Internal quality control (IQC) measures constantly produced the expected results: they included positive and negative control plates that did not show any macroscopic or microscopic contamination, ruling out culture medium contamination. Processing sterile distilled water instead of specimen did not lead to contamination, suggesting that the contamination source was the specimen itself.

**Table 2** Clinical and radiological presentation of included patients

| | Overall ($N$ = 208) *n* (%) | HIV-positive ($n$ = 117) *n* (%) |
|---|---|---|
| Clinical signs | | |
| Productive cough | 200 (96.1) | 110 (90.0) |
| Chest pain | 188 (90.4) | 103 (88.0) |
| Reported fever | 182 (87.5) | 102 (87.2) |
| Haemoptysis | 24 (11.5) | 10 (8.6) |
| Night sweats | 169 (81.2) | 97 (82.9) |
| Reported weigh loss | 26 (12.5) | 17 (14.7) |
| Loss of appetite | 162 (77.9) | 93 (79.5) |
| Chest X-ray findings | | |
| Cavities | 68 (32.7) | 40 (34.2) |
| Infiltration | 154 (74.0) | 96 (82.0) |
| Condensation | 134 (64.4) | 73 (62.4) |
| Pleural effusion | 13 (6.3) | 9 (7.7) |
| Intrathoracic adenopathy | 42 (20.2) | 24 (20.5) |
| Miliary | 1 (0.5) | 1 (0.8) |
| No X-ray | 2 (1) | 1 (0.8) |

HIV = human immunodeficiency virus.

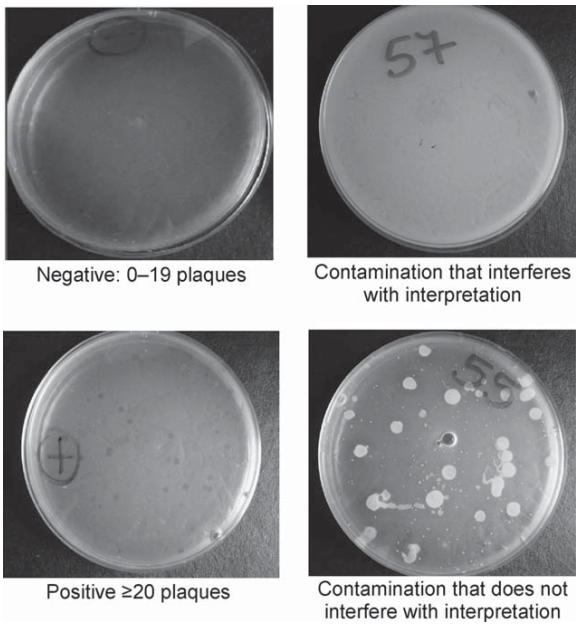


**Figure 2** *FASTPlaque*TB results.

After exclusion of contaminated cultures and cases with no *FASTPlaque*TB results, the proportion of positive culture results did not significantly vary between patients with interpretable *FASTPlaque*TB results (15/88, 17.1%) and those with non-interpretable results (16/102, 15.7%, $P$ = 0.8). The test performance could therefore be evaluated in 102 patients after exclusion of the non-interpretable *FASTPlaque*TB results (Table 4). The test sensitivity overall was 31.2% (95%CI 12.1–58.5) and specificity was 94.9% (95%CI 86.8–98.4); they were respectively 33.3% (95%CI 9.9–65.1) and 93.9% (95%CI 83.1–98.7) in HIV-infected patients. Performance was not evaluated in HIV-negative patients due to the small sample size ($n$ = 18).

Inter- and intra-reader reproducibility was satisfactory, with a κ of 0.81 (95%CI 0.76–0.84) and 0.92 (95%CI 0.85–0.94), respectively.

**Table 3** Results of *FASTPlaque*TB by *M. tuberculosis* culture results ($N$ = 208)

| | Culture results, *n* (%) | | | |
|---|---|---|---|---|
| *FASTPlaque*TB results | Positive | Negative | Contaminated | Not performed |
| Positive | 5 (15.6) | 5 (1.8) | 0 | 0 |
| Negative | 11 (34.4) | 81 (49.7) | 4 (40.0) | 2 |
| Indeterminate* | 15 (50.0) | 73 (47.2) | 6 (60.0) | 1 |
| Procedure failure | 1 | 4 | 0 | 0 |
| Total | 32 | 163 | 10 | 3 |

* Contamination that interferes with interpretation.

**Table 4** *FASTPlaque*TB performance*

| | Number of cultures | | | | | |
|---|---|---|---|---|---|---|
| | All cases | | | HIV-infected | | |
| | Positive | Negative | Total | Positive | Negative | Total |
| *FASTPlaque*TB | | | | | | |
| Positive | 5 | 5 | 10 | 4 | 3 | 7 |
| Negative | 11 | 81 | 92 | 8 | 46 | 54 |
| Total | 16 | 86 | 102 | 12 | 49 | 61 |
| | % (95%CI) | | | % (95%CI) | | |
| Sensitivity | 31.2 (12.1–58.5) | | | 33.3 (9.9–65.1) | | |
| Specificity | 94.2 (86.9–98.1) | | | 93.9 (83.1–98.7) | | |
| Positive predictive value | 50.0 (18.7–81.3) | | | 57.1 (18.4–90.1) | | |
| Negative predictive value | 88.0 (79.6–93.9) | | | 85.2 (72.9–93.4) | | |
| Positive likelihood ratio | 5.4 (1.8–15.3) | | | 5.5 (1.5–19.1) | | |
| Negative likelihood ratio | 0.7 (0.5–0.9) | | | 0.7 (0.4–0.9) | | |

* A total of 102 cases were analysed after exclusion of *FASTPlaque*TB™ and culture-contaminated results. Of these, 61 were HIV-positive, 18 HIV-negative and for 23 the HIV status was unknown.
HIV = human immunodeficiency virus; CI = confidence interval.

Considering the operational aspects of *FAST-Plaque*TB, a median of six specimens (interquartile range [IQR] 4–8) were tested per week. The median duration of the weekly sterilisation of containers was 2.8 h (IQR 2.5–3.1), and it was 2.6 h (IQR 2.3–3.1) for the weekly preparation of reagents. To perform the test itself, the median duration of sputum preparation (day 1) was 2.4 h (IQR 2.1–2.5), 2.5 h (IQR 2.3–3.0) for the *FASTPlaque*TB assay procedure (day 2) and 19 s (IQR 15–38) for reading the plate. At the time of the study, it cost €7/test to perform *FAST-Plaque*TB, including the cost of the test (€2.5) and the cost of other reagents and consumables. Upgrading of the peripheral laboratory, together with the service and maintenance costs of the additional equipment during the study period, amounted to approximately €20 000. This figure does not include the costs of external technical assistance.

## DISCUSSION

To our knowledge, this is the first reported study to evaluate *FASTPlaque*TB in the operational setting of a peripheral health clinic. Despite the good storage conditions, at +4°C, of specimens between collection and processing, strict use of aseptic techniques and standard specimen decontamination, as recommended by the manufacturer, 80% of the plates were contaminated. This resulted in the absence of results for half of the patients. The low rate of culture contamination (4.9%) indicates that the decontamination was adequate for *M. tuberculosis* culture on LJ medium but not for preventing *FASTPlaque*TB contamination. It is possible that the delay in processing a batch of specimens (up to 1 week) may have contributed to the high rates of contamination. Furthermore, most of the identified contaminants were spore-forming bacilli—an indication of environmental contamination that may have occurred during specimen collection, which was done outdoors in a dusty environment. This excessively high contamination rate (40%) has also been reported in a previous study conducted in a tertiary hospital in Zambia.[20]

In this study, measurement of the test's performance was limited by the small sample size due to the early interruption of the study. The results should therefore be interpreted with caution. The sensitivity of the test in smear-negative TB suspects, compared with LJ culture, is lower (31%, 95%CI 12.1–58.5) than that reported in South Africa (54%) and Pakistan (77%).[10,11,21] Nevertheless, our results are consistent with the heterogeneity of sensitivity (13–78%) and high specificity (89–99%) in smear-negative specimens reported by a meta-analysis of bacteriophage-based tests.[9] The delay in specimen processing of up to 1 week in our study, and the high proportion of HIV infection, could impact the extent of viable mycobacteria present in specimens and explain the low sensitivity.[9] The positive (5.4) and negative (0.7) likelihood ratios did not provide strong evidence that a *FAST-Plaque*TB result can respectively confirm or exclude TB in smear-negative suspects. These ratios measure how a particular test result predicts the risk of abnormality, which is not the case of sensitivity and specificity, and are independent of the disease prevalence in the sample size, which is another advantage compared to predictive values.[18]

Since the study was conducted, the manufacturer of *FASTPlaque*TB has developed an antimicrobial supplement (NOA: nystatin+oxacillin+aztreonam) to be used with the test. This supplement inhibits the growth of contaminating bacterial and fungal organisms commonly found in respiratory specimens, and significantly reduces plate contamination. The test performance was not affected when assessed in combination with the *FASTPlaque*-Response test for rapid identification of rifampicin (RMP) resistance, but no data are available on its use in combination with *FAST-Plaque*TB.[22,23] If the contamination problem can be solved without compromising performance, we be-

lieve it may be possible to perform the test in a peripheral laboratory that is upgraded. However, upgrading a laboratory to the level required to perform the test and maintaining it at that level is extremely difficult in limited-resource settings, even with the external support provided in this example. In addition to the cost, the installation of specialist equipment, and the requirements for uninterrupted overnight electrical power for incubation and for equipment maintenance support present challenges in limited-resource settings.

The study also highlights the limitations of the *FASTPlaque*TB kits (batch of eight tests) for settings with moderate specimen throughput, where specimens need to be processed by batch and the delay in producing results is therefore increased.

The culture positivity rate among the smear-negative TB suspects was relatively low (16%), if we consider the high degree of TB suspicion in this study. The relatively low proportion of patients with CXR suggestive of TB (54.8%), the high HIV infection rate (56.2%) and the high level of microscopy performance reported in a previous study conducted in the laboratory during the same period, may explain the low culture positivity.[15,24] The male:female sex ratio of smear-negative TB suspects was unexpectedly low and should be investigated further.

In conclusion, if the problems of contamination can be solved, *FASTPlaque*TB could be used in the few laboratories that already perform *M. tuberculosis* culture in resource-limited countries. The test's rapidity (2 days) and the possibility of using the same phage-base method for rapid identification of RMP susceptibility could provide further reasons for using the test. Based on our experience, introducing such a test in a peripheral clinic after upgrading the laboratory is feasible but expensive, complex and difficult to maintain. Several conditions therefore need to be met before recommending such an investment: 1) further evaluation of its performance in smear-negative suspects as compared to *M. tuberculosis* culture as well as simple methods to optimise smear microscopy, such as the specimen concentration method and fluorescence microscopy;[25,26] 2) considering the relatively high bacilli threshold of *FASTPlaque*TB, its specificity should be evaluated in combination to the NOA supplement and in HIV-infected patient subgroups, which are more likely to have a low bacillary load; 3) several modifications, such as the reduction of sample manipulations and the development of smaller kits to be used in laboratories conducting only a few tests per day (this would allow for daily processing of specimens) could make the *FASTPlaque*TB more user friendly and cost-effective.

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**RÉSUMÉ**

**OBJECTIVE : Evaluer les performances et la faisabilité du *FASTPlaque*TB™ chez les patients frottis-négatifs suspects de tuberculose dans une clinique périphérique après amélioration des capacités du laboratoire.**

**MÉTHODES : Les patients suspects frottis-négatifs étaient définis par l'association d'une toux ⩾2 semaines, deux résultats de crachats frottis-négatifs, l'absence d'amélioration clinique après 1 semaine d'amoxicilline et une radiographie thoracique anormale. Un crachat était collecté, décontaminé et divisé en deux : une moitié testée sur place avec le *FASTPlaque*TB et l'autre moitié mise en culture sur milieu de Löwenstein-Jensen à l'Institut de Recherche médicale de Kenya. La sensibilité et spécificité du test étaient évaluées chez tous les patients et chez les patients positifs au virus de l'immunodéficience humaine (VIH). Le taux de contamination et les ressources nécessaires à l'introduction du *FASTPlaque*TB dans le laboratoire en évaluaient la faisabilité.**

**RÉSULTATS : Sur 208 patients inclus, 56,2% étaient VIH-positifs. Sur 203 résultats de *FASTPlaque*TB, 95 (46,8%) n'étaient pas interprétables en raison d'une contamination, ce qui a conduit à l'interruption de l'étude. Le test avait une sensibilité et une spécificité globales de 31,2% (95%CI 12,1–58,5) et 94,9% (95%CI 86,8–98,4) et de 33,3% (95%CI 9,9–65,1) et 93,9% (95%CI 83,1–98,7) chez les patients VIH-positifs. L'amélioration des capacités du laboratoire pour l'utilisation du *FASTPlaque*TB a coûté 20 000€.**

**CONCLUSION : Les performances du *FASTPlaque*TB sont décevantes dans ce type de contexte. Outre la réduction du taux de contamination et l'amélioration des capacités du laboratoire, son utilisation dans une clinique périphérique nécessiterait des évaluations supplémentaires chez les patients VIH-positifs et frottis-négatifs et une optimisation du test pour une meilleure utilisation.**

**RESUMEN**

**OBJETIVO : Evaluar el rendimiento diagnóstico y la factibilidad de la prueba *FASTPlaque*TB™ en los consultorios periféricos, en pacientes con presunción diagnóstica de tuberculosis (TB) y baciloscopia negativa, una vez optimizados los laboratorios.**

**MÉTODOS : Se definieron como casos presuntos de TB con baciloscopia negativa, los pacientes con tos de ⩾2 semanas de duración y dos baciloscopias negativas, que no respondieron al tratamiento de una semana con amoxicilina y que presentaron imágenes anormales en la radiografía de tórax. Se recogió una muestra de esputo y una vez descontaminada se dividió en dos alícuotas, una para la prueba *FASTPlaque*TB en el laboratorio de la clínica y otra para cultivo en medio de Löwenstein-Jensen en el Instituto de Investigación médica de Kenya. Se evaluó la sensibilidad y la especificidad de la prueba en todos los pacientes y en los pacientes con infección por el virus de la inmunodeficiencia humana (VIH). La factibilidad se evaluó con respecto a la contaminación y a los recursos del laboratorio para la optimización.**

**RESULTADOS : De los 208 pacientes incluidos, 56,2% presentaron infección por el VIH. De los 203 ensayos con *FASTPlaque*TB, 95 (46,8%) presentaron una contaminación que interfirió con la interpretación de los resultados y exigió la interrupción del estudio. La prueba demostró una sensibilidad de 31,2% (95%IC 12,1–58,5) y una especificidad de 94,9% (IC95% 86,8–98,4) en todos los pacientes y de 33,3% (IC95% 9,9–65,1) y 93,9% IC95% 83,1–98,7), respectivamente, en pacientes infectados por el VIH. La optimización del laboratorio tuvo un costo de €20 000.**

**CONCLUSIÓN : La prueba *FASTPlaque*TB no ofreció un rendimiento satisfactorio en este entorno. La introducción de la prueba en los consultorios periféricos requeriría, además de disminuir el índice de contaminación y el costo de optimización del laboratorio, que se practiquen nuevas evaluaciones en pacientes con baciloscopia negativa y coinfección por el VIH y se adapte el ensayo a fin de facilitar su ejecución.**