

Capilia test for identification of *Mycobacterium tuberculosis* in MGIT™-positive cultures

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SUMMARY

BACKGROUND: The performance of the Capilia test for rapid identification of *Mycobacterium tuberculosis* complex (MTC) in Mycobacterium Growth Indicator Tube (MGIT) positive samples with contaminating organisms is not well documented.

OBJECTIVE: To assess the diagnostic yield of the Capilia test in the rapid identification of MTC in MGIT-positive cultures.

DESIGN: A total of 459 selected sputum samples were cultured using BACTEC™ MGIT™ 960. Tubes flagged positive by the MGIT instrument (MGIT-positive) were examined for acid-fast bacilli and cording in smears, spotted on blood agar (BA), subcultured for biochemical tests and tested using the Capilia test. Based on smear and growth on BA, MGIT-positive tubes were grouped into MGIT true-positive, MGIT-positive with contami-

nation and MGIT contamination. Performance parameters of Capilia test such as sensitivity, specificity, efficiency, and positive and negative predictive values (PPV, NPV) for each of these groups were determined against biochemical tests as gold standard.

RESULTS: Of the 346 MGIT-positives, respectively 233, 73 and 40 were MGIT true-positive, MGIT-positive with contamination and MGIT contamination. For the three groups, the PPV and NPV of the Capilia test were respectively 97%, 96% and 100%, and 32%, 27% and 60%.

CONCLUSION: In settings with high contamination of MGIT cultures, the performance of the Capilia test is diminished.

KEY WORDS: Capilia; *M. tuberculosis*; MGIT™ 960; rapid identification

USE OF LIQUID CULTURE for early detection and identification of *Mycobacterium tuberculosis* from clinical specimens has been internationally recommended.¹ Due to its rapidity, reliability and ease of operation, the BACTEC™ MGIT™ 960 (MGIT) system (BD, Franklin Lakes, NJ, USA) is being widely adopted to replace conventional solid culture methods.² The system is efficient in isolating both *M. tuberculosis* complex (MTC) and other pathogenic mycobacteria.³ However, it lacks a protocol for definitive identification of MTC in MGIT-positive cultures, and presumptive diagnosis is based on the presence of acid-fast bacilli (AFB) and cording in Ziehl-Neelsen (ZN) stained smears.⁴ Another limiting factor is that drug susceptibility testing (DST) should be performed within 5 days of an MGIT-positive result.⁵ Existing conventional identification tests are time consuming, and available rapid molecular methods require additional equipment and technical skills, and are prohibitively expensive for regular use in resource-poor laboratories.⁶ To fully realise the potential benefits of such tests, there is therefore an urgent need for a

simple test that rapidly confirms MTC from MGIT-positive cultures.⁷

The Capilia TB-Neo assay (TAUNS Laboratories, Numazu, Japan),^{*} is an immunochromatographic technique for detecting secretory protein MPB64, produced by MTC. It employs a nitrocellulose membrane with specific anti-MPB64 mouse monoclonal antibody immobilised on it. The gold-coated antibody forms a complex with the antigen, which is indicated by the appearance of a purple band on the test area of the strip. An internal quality control is included on the strip.⁸ The test, which can be completed in 15 min for identification of MTC in AFB-positive liquid cultures, does not require additional technical skills or equipment. The assay has been reported to have high sensitivity and specificity, ranging from respectively 92% to 99% and 97% to 100%.⁹⁻¹² In the present study, the performance of the Capilia kit in

*Note that mention of the brand name does not mean that any of the authors or their respective institutions/organisations endorse said product.

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Article submitted 20 May 2011. Final version accepted 17 November 2011.

identifying MTC in MGIT-positive cultures was compared with conventional biochemical tests (i.e., niacin test and susceptibility to para-nitrobenzoic acid [PNB] at 500 µg/ml) as gold standard.

MATERIALS AND METHODS

Sputum samples

Sputum samples used in the study were from patients in on-going clinical trials or from patients suspected of drug-resistant tuberculosis (TB). A total of 459 samples were selected, of which 333 were AFB smear-positive and 126 were smear-negative. Institutional ethical committee clearance had already been obtained for collection of sputum samples from the patients for routine mycobacteriological investigations. All 459 sputum samples, collected from February to July 2010, were processed using the modified Petroff's method. Briefly, about 5 ml of sputum was homogenised with an equal volume of 4% sodium hydroxide in a mechanical shaker for 15 min, and centrifuged at 3000 × g for 15 minutes. Traces of the alkali from the deposit were removed by washing with 20 ml of sterile distilled water by a second centrifugation. The resultant pellet was suspended in 0.06 M phosphate-buffered saline (pH 6.8) and used for inoculating MGIT tubes, as per the manufacturer's protocol.⁵ Tubes flagged as positive by the MGIT system (MGIT-positives) were removed from the system and incubated at 37°C until they had been subjected to all of the tests simultaneously on any day from 1 to 5 days.

AFB smear and inoculation on media

All MGIT-positive tubes were subjected to ZN staining to observe AFB and cording, inoculated onto blood agar (BA) to check for contamination, subcultured onto plain Löwenstein-Jensen (LJ) media to perform the niacin test, and onto LJ containing PNB to determine susceptibility to the latter (Figure 1).¹³

The Capilia test

The Capilia test was performed on all the MGIT-positives as per the manufacturer's protocol, after coding the tubes.¹⁴ Briefly, 100 µl of the culture was placed in the sample area of the test strip. Presence of MTC in the culture was indicated by the appearance of a red-purple band within 15 min. The result was valid only if the internal control included in the test strip showed a purple band. The MGIT tubes were immediately stored at 4°C; the period of storage ranged from 1 to 6 months.

Reproducibility of the Capilia test

A total of 34 MGIT-positive tubes stored at 4°C were selected, coded and retested using the Capilia test.

Quality control

M. tuberculosis H37Rv and *M. smegmatis* were included as respectively positive and negative controls

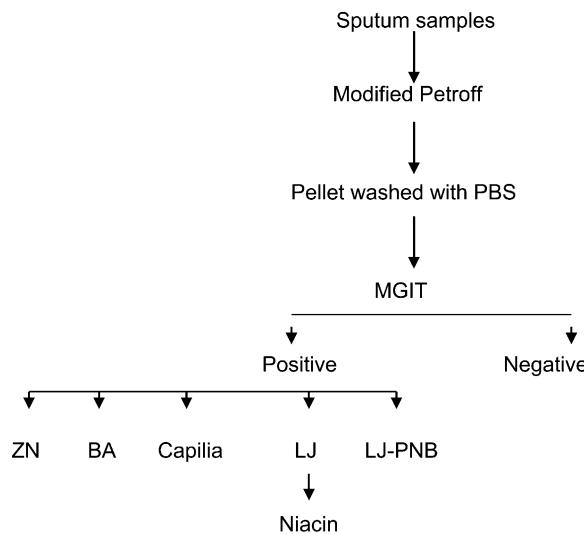


Figure 1 Work flow. PBS = phosphate-buffered saline; MGIT = *Mycobacterium* Growth Indicator Tube; ZN = Ziehl-Neelsen stain; BA = blood agar; LJ = Löwenstein-Jensen medium; LJ-PNB = LJ medium with para-nitrobenzoic acid.

with every batch of cultures tested. A panel of cultures, consisting of 10 clinical isolates of MTC, one laboratory strain of *M. bovis* bacille Calmette-Guérin (BCG; Trudeau) and seven non-tuberculous mycobacteria (NTM) strains (*M. flavescens*, *M. gordonaiae*, *M. kansasii*, *M. phlei*, *M. szulgai*, *M. fortuitum* and *M. thermoresistible*) grown in MGIT, were coded and included as controls.

Analysis

MGIT-positives were classified based on the presence of AFB and/or cording in smears, and growth of contaminating organisms on BA as follows: AFB/cord-positive, BA-negative = MGIT true-positive; AFB/cord-positive, BA-positive = MGIT-positive plus contamination; and AFB/cord-negative, BA-positive = MGIT contamination. Mycobacterial cultures were identified based on the following conventional criteria: niacin-positive, PNB-negative = MTC; niacin-negative, PNB-positive = NTM; niacin-positive, PNB-positive = mixture; no growth on LJ = MTC-negative. For the purposes of analysis, mixed cultures were considered as MTC, and NTM cultures were considered as MTC-negative.

RESULTS

Presumptive identification of MTC using AFB staining

Of 459 samples inoculated onto MGIT tubes, 346 were MGIT-positive, 109 were MGIT-negative and four were clear cases of contamination and thus discarded. Among the 346 MGIT-positives, 233 were MGIT true-positives, 73 were MGIT-positive with contamination, and 40 were MGIT contamination.

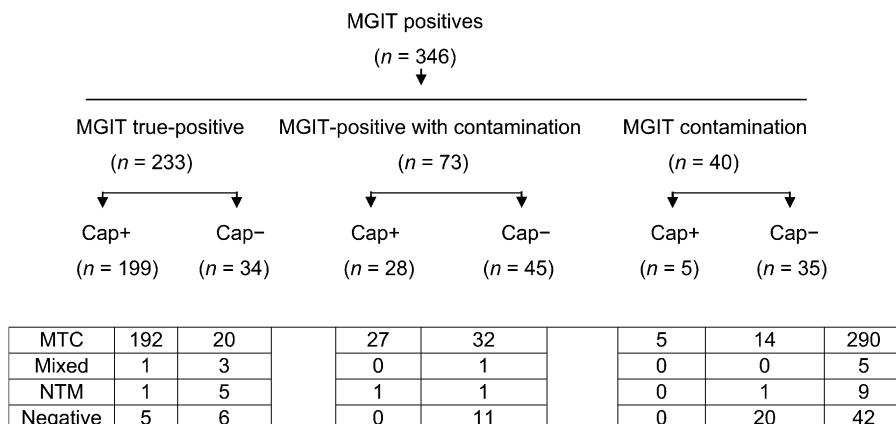


Figure 2 Performance of the Capilia test in comparison with conventional tests. MGIT = Mycobacterium Growth Indicator Tube; Cap+ = Capilia positive; Cap- = Capilia negative; MTC = *Mycobacterium tuberculosis* complex; Mixed = both MTC and NTM present in culture; NTM = non-tuberculous mycobacteria.

Identification of MTC by conventional biochemical tests

Of the 346 MGIT-positive cultures, conventional biochemical tests identified 290 as MTC, 5 as mixed cultures, 9 as NTM and 42 as negatives.

Efficiency of the Capilia test

The Capilia test was performed on all 346 MGIT-positive cultures. Of the 233 MGIT true-positive cultures, the Capilia test yielded 199 positives: 192 MTC, 1 mixed culture, 1 NTM and 5 negatives. There were 34 Capilia negatives, comprising 20 MTC, 3 mixed cultures, 5 NTM and 6 negatives (Figure 2). In this group, sensitivity, specificity, efficiency, positive predictive value (PPV) and negative predictive value (NPV) were respectively 89.4% (193/216), 65% (11/17), 88% (204/233), 97% (193/199) and 32% (11/34).

In the second group of 73 cultures that were MGIT-positive with contamination, Capilia was positive for 28: 27 MTC and 1 NTM. The test was negative for 45 cultures: 32 MTC, 1 mixed, 1 NTM and 11 negatives. In this group, sensitivity, specificity, efficiency, PPV and NPV were respectively 45% (27/60), 92% (12/13), 53% (39/73), 96% (27/28) and 27% (12/45).

In the third group, consisting of the 40 MGIT contaminated cultures, there were five Capilia positives, all of them MTC. Among the remaining 35 Capilia negatives, there were 14 MTC, 1 NTM and 20 negatives. In this group, sensitivity, specificity, efficiency, PPV and NPV were respectively 26% (5/19), 100% (21/21), 65% (26/40), 100% (5/5) and 60% (21/35).

Overall, the test was positive for 225/295 MTC cultures (including 5 mixed cultures) and negative for 44/51 MTC negatives (including 9 NTM). There were 70 false-negatives (66 MTC and 4 mixed) and 7 false-positives (2 NTM and 5 MTC-negative; Table). The sensitivity, specificity, efficiency, PPV and NPV were found to be respectively 76%, 86%, 78%, 97% and 39%.

Table Performance of the Capilia test with cultures identified by conventional tests

| | Conventional | | |
|----------|--------------|----------|-------|
| | Positive | Negative | Total |
| Capilia | | | |
| Positive | 225 | 7* | 232 |
| Negative | 70 | 44† | 114 |
| Total | 295‡ | 51 | 346 |

* 5 MTC negatives, 2 NTM.

† 37 MTC negatives, 7 NTM.

‡ 290 MTC, 5 mixed cultures.

MTC = *Mycobacterium tuberculosis* complex; NTM = non-tuberculous mycobacteria.

Reproducibility of the Capilia test

Among 34 MGIT-positives that were retested by Capilia, 22 yielded the same results (17 positives and 5 negatives). Of the remaining 12 cultures, 11 that were originally Capilia-negative yielded positive results on retesting, while one tube that was initially Capilia-positive yielded a negative result on retesting.

Quality control

During the course of the study, *M. tuberculosis* H37Rv and *M. smegmatis*, included as internal controls, were respectively Capilia-positive and -negative on all 18 occasions. All the 10 clinical strains of MTC were Capilia-positive, and all the seven NTM strains were Capilia-negative. The laboratory strain *M. bovis* BCG (Trudeau) was Capilia-negative.

DISCUSSION

The non-radiometric MGIT™ 960 system, despite certain advantages,¹⁵ is hampered by the lack of a rapid test for the identification of MTC, unlike the BACTEC 460 system, which makes use of the NAP (*p*-nitro- α -acetylaminoo- β -hydroxypropionophenone) test.¹⁶ Nucleic acid amplification tests such as the BD

ProbeTec ET (CTB) assay (BD, Sparks, MD, USA), AccuProbe (Gen-Probe Inc, San Diego, CA, USA) and INNO-LiPA (Innogenetics, Ghent, Belgium) are labour-intensive and expensive.¹¹ The Capilia TB-Neo kit is reported to be simple and rapid for the identification of MTC, with high sensitivity and specificity.¹⁷ With this background, the current study was designed to assess the performance of the Capilia test in identifying MTC in MGIT-positive cultures compared to conventional biochemical tests as the gold standard.

Similar to earlier findings,^{10–12,17} the test correctly identified all MTC and NTM strains in the panel of known cultures included in the study, except for *M. bovis* BCG. It is known that *mpb64* is absent from some strains of *M. bovis* BCG.¹⁸ However, contrary to earlier findings reporting high levels of sensitivity and specificity for the test, presumably using pure growth of MTC in the MGIT tubes,^{9–12} this study, in a setting with high contamination rates, showed lower sensitivity (76% [225/295]) and specificity (86% [44/51]) when all MGIT-positive tubes were considered for analysis. There were 23 Capilia false-negatives in the MGIT true-positive group (including 20 MTC and 3 mixed), 33 in the MGIT-positive plus contamination group (including 32 MTC and one mixed) and 14 in the MGIT contamination group. Six of the 23 Capilia false-negative/MGIT true-positive group yielded Capilia-positive results on repeated testing. Of the remaining 14 cultures, nine exhibited low growth units and flagged positive late. Growth on LJ showed low grade after subculture of these cultures. Hence, false negativity among these cultures could be attributed to the low mycobacterial counts in the MGIT tubes. These observations suggest the need for prolonged incubation of MGIT-positive/Capilia-negative tubes and retesting them using the Capilia test. The observations of Camilla et al., which extended the period of incubation of MGIT positives for adequate cording and increased identification of MTC,¹⁹ supports our suggestion. It should be noted that for the Capilia test to become positive, at least 1.2×10^6 colony-forming units/ml of MTC need to be present in the culture.¹⁴ Capilia negativity in some of the cultures may also be attributed to the possibility of mutations in *mpb64*, as reported earlier,¹² which would require confirmation with DNA sequencing.

False negativity in three mixed cultures in the MGIT true-positive group could be attributed to masking of the antigen by the NTM present, as the smears of these cultures were rich in bacilli. Similarly, Capilia false negativity in 33 (including one mixed) of the MGIT-positive plus contamination group, and in 14 of the MGIT contamination group, could be attributed to the contaminating organisms. Presence of MTC in the above cultures was confirmed by smear and/or subculture on LJ. In addition, four of the false negatives (two each in the MGIT-positive with contamination group and the MGIT contamination group)

yielded positive results on repeat Capilia testing. Repeat Capilia testing for all MGIT false-negatives and for all MTC isolates from LJ subculture could not be performed due to the limited availability of the test strips.

A total of 27 MTC cultures in the MGIT-positive plus contamination group and five of the MGIT contamination group were Capilia-positive despite the presence of contaminating organisms. It appears that the bacterial load of contaminating organisms along with MTC was crucial in determining the Capilia result. Decontamination and retrieval of pure growth of MTC from the tubes of the MGIT-positive plus contamination and the MGIT contamination groups and retesting with Capilia might therefore yield positive results.

In this study there were seven Capilia false-positives (five MTC negatives and two NTM). The reasons for these were unclear. However, it was observed that the primary cultures of these specimens on LJ were also negative for MTC. The high rate of culture positivity seen in the study may be attributed to the fact that the sputum samples were so selected.

It is well known that the contamination rate can be high with liquid cultures, whereas in solid culture it is often <3%. This study witnessed 33% contamination (113/346), including 21% (73/346) that showed AFB along with contamination. Most of these contaminating organisms were aerobic spore bearers (data not shown). It is known that these contaminants can be prevented from growing on LJ media due to the presence of malachite green. This is well demonstrated in the present study, in which 82/113 (73%) contaminated MGIT tubes yielded pure MTC on LJ media. The continued presence of aerobic spore bearers having survived the action of the decontaminating agent, and thus subsequently causing contamination of liquid cultures, has been repeatedly reported.²⁰ To reduce contamination in liquid cultures, Peres et al. have tried doubling the concentrations of PANTA (polymyxin B, amphotericin B, nalidixic acid, trimethoprim and azlocillin) in the MGIT tubes,²¹ while Kumar et al. have used phagebiotics to control contamination.²⁰ In this study, the sputum samples were processed in a Class I biosafety cabinet in a high-volume laboratory which had eight such cabinets in a single room. Several precautions, including the use of Class II biosafety cabinets, need to be followed to minimise the contamination of MGIT tubes and to achieve the maximum potential of Capilia.

This study is the first to evaluate the performance of the Capilia test in MGIT positives that carry contaminating organisms along with MTC, and suggests ways to overcome false-negative results. It will find relevance in settings with similar contamination rates for performing the test. It may also be of interest to know the yield of MTC and Capilia positives among MGIT negatives.

CONCLUSION

The current study demonstrates the potential use of the Capilia TB-Neo kit for rapid identification of MTC in MGIT-positive cultures with a high PPV. However, the efficiency of the Capilia test appears to be affected by a low mycobacterial load in the MGIT-positive tubes. Several precautions to minimise the contamination of MGIT tubes should be followed to achieve the maximum potential of the Capilia test.

Acknowledgements

The technical support provided by the staff of the Department of Bacteriology, National Institute for Research in Tuberculosis (NIRT), Chennai, India, is gratefully acknowledged. This study was supported in part by the World Health Organization (WHO), Geneva, Switzerland, with financial assistance provided by the United States Agency for International Development, Washington DC, USA, under the WHO/NIRT Collaborative Model DOTS Project.

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RÉSUMÉ

CONTEXTE : Les informations concernant les performances du test Capilia pour l'identification rapide du complexe *Mycobacterium tuberculosis* (MTC) dans les souches positives avec l'outil MGIT™ et comportant des agents contaminants ne sont pas bien documentées.

OBJECTIF : Evaluer le rendement du test Capilia pour l'identification rapide de MTC dans les cultures positives avec MGIT.

SCHÉMA : On a mis en culture 459 échantillons sélectionnés de crachats dans le système MGIT 960. Les tubes déclarés positifs par l'outil (MGIT-positifs) ont été examinés à la recherche des bacilles acido-résistants et de la présentation sous forme de cordes dans les frottis, inoculés sur une gélose au sang (BA), mis en subculture pour les tests biochimiques et finalement testés par Capilia. En se basant sur le frottis et sur le développement sur BA, les tubes MGIT-positifs ont été regroupés en

MGIT vrai-positif, MGIT-positif avec contamination et MGIT contaminés. On a déterminé en prenant comme standard les tests biochimiques les paramètres de performance du test Capilia tels que la sensibilité, la spécificité, l'efficience et les valeurs prédictives positive et négative (PPV et NPV) pour chacun de ces groupes.

RÉSULTATS : Sur 346 souches déclarées comme MGIT-positives, 233 ont été MGIT vrai-positives, 73 MGIT-positives avec contamination et 40 MGIT avec contamination. La PPV de Capilia a été respectivement de 97%, 96% et 100% dans les trois groupes et la NPV respectivement de 32%, 27% et 60% pour les trois mêmes groupes.

CONCLUSION : Dans les contextes où la contamination des cultures MGIT est fréquente, les performances du test Capilia sont diminuées.

RESUMEN

MARCO DE REFERENCIA: No se cuenta con información bien documentada sobre la prueba Capilia para la detección rápida del complejo *Mycobacterium tuberculosis* en muestras con un cultivo positivo en el sistema MGIT™ y con microorganismos contaminantes.

OBJETIVO: Se buscó evaluar el rendimiento diagnóstico de la prueba Capilia de detección rápida de *M. tuberculosis* en los cultivos positivos con el sistema MGIT.

MÉTODO: Se escogieron 459 muestras de esputo y se pusieron en cultivo en el sistema MGIT 960. Los tubos señalados como positivos por MGIT se examinaron en frotis en busca de bacilos acidorresistentes y de formación de cordones en serpentina, se sembraron en agar sangre (BA), se subcultivaron para pruebas bioquímicas y se sometieron a la prueba Capilia. Con base en el examen del frotis y el crecimiento en BA, las muestras señaladas como MGIT positivas se clasificaron en muestras

verdaderamente positivas, muestras positivas contaminadas y muestras contaminadas. Se determinaron las características de sensibilidad, especificidad, eficacia y valor pronóstico positivo (PPV) y negativo (NPV) de la prueba Capilia con cada uno de estos grupos, tomando como referencia las pruebas bioquímicas.

RESULTADOS: De las 346 muestras MGIT positivas, 233 se clasificaron como positivas, 73 como verdadero positivas contaminadas y 40 como muestras contaminadas. El PPV de la prueba Capilia con estos grupos de muestras fue 97%, 96% y 100% respectivamente y el NPV fue 32%, 27% y 60%.

CONCLUSIÓN: En los entornos donde existe una alta proporción de cultivos contaminados en el sistema MGIT se disminuye el rendimiento diagnóstico de la prueba Capilia.