

# Clinical profiling and use of loop-mediated isothermal amplification assay for rapid detection of *Mycobacterium tuberculosis* from sputum

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## Abstract

**Background:** Tuberculosis is a leading cause of death worldwide. Rapid detection of *Mycobacterium tuberculosis* from sputum is essential for early treatment. Loop-mediated isothermal amplification (LAMP) is a rapid and sensitive method for the detection of *M. tuberculosis* complex DNA.

**Objectives:** To compare the performance of LAMP with conventional methods for the detection of *M. tuberculosis* in sputum.

**Materials and methods:** A total of 202 sputum samples were collected from patients with clinical suspicion of tuberculosis. The samples were analyzed by LAMP, culture, and Xpert MTB/RIF.

**Result:** Of 202 samples, 14 (7.0%) were positive by LAMP, 13 (6.4%) by culture, and 1 (0.5%) by Xpert MTB/RIF. The sensitivity and specificity of LAMP were 100% (95% CI 78.33-100.00) and 99.3% (95% CI 98.11-100.00), respectively. The sensitivity and specificity of culture were 100% (95% CI 84.1-100.0) and 99.3% (95% CI 98.11-100.0), respectively. The sensitivity and specificity of Xpert MTB/RIF were 100% (95% CI 84.1-100.0) and 99.3% (95% CI 98.11-100.0), respectively.

**Conclusion:** LAMP is a rapid and sensitive method for the detection of *M. tuberculosis* in sputum. It can be used as a point-of-care test for the rapid diagnosis of tuberculosis.

**Key words:** Tuberculosis, *M. tuberculosis*, LAMP, sputum

Introduction: Tuberculosis (Tb) is a leading cause of death worldwide. The World Health Organization (WHO) estimates that there are 10 million people living with Tb globally. In Nepal, Tb is also a major public health problem. The National Tuberculosis Control Program (NTP) in Nepal has been successful in reducing the burden of Tb, but there is still a need for rapid and accurate diagnostic methods. Loop-mediated isothermal amplification (LAMP) is a rapid and sensitive method for the detection of *M. tuberculosis* complex DNA. It is a simple, easy-to-use, and cost-effective method that can be performed at a constant temperature of 60-65°C. In this study, we compared the performance of LAMP with conventional methods for the detection of *M. tuberculosis* in sputum.

Methods: A total of 202 sputum samples were collected from patients with clinical suspicion of tuberculosis. The samples were analyzed by LAMP, culture, and Xpert MTB/RIF. The LAMP assay was performed using a set of six primers that target the IS6110 region of the *M. tuberculosis* complex genome. The results were compared with those of culture and Xpert MTB/RIF.

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**Table 1** Clinical characteristics of patients with confirmed dengue fever

| Clinical characteristics   | N (%)      |
|----------------------------|------------|
| Age (years)                | 42(23.2)   |
| Gender                     | 14 (3.2)   |
| Duration of illness (days) | 13 (2.9)   |
| Signs and symptoms         | 133 (29.8) |
| Headache                   | 1 (34.1)   |
| Joint pain                 | 1 (44.4)   |
| Others                     |            |
| a) Rash                    | 101(22.5)  |
| b) Bleeding                | 10 (2.2)   |
| c) Abdominal pain          | 1 (3.20)   |

**Table 2** Laboratory findings in patients with confirmed dengue fever

| Test                             | Positive N (%) | Negative N (%) |
|----------------------------------|----------------|----------------|
| Haemoglobin (g/dl)               | 101(100%)      | 101(100%)      |
| Platelets (x10 <sup>9</sup> /L)  | 100(99.0%)     | 102(100.0%)    |
| Prothrombin time (sec)           | 103(100.0%)    | 103(100.0%)    |
| Aspartate aminotransferase (U/L) | 11 (10.7%)     | 1 (0.98%)      |

**Table 3** Microscopic and radiological findings in patients with confirmed dengue fever

| Microscopy (M) | Culture (C) | LAMP | X-ray (X) | Number (%) |
|----------------|-------------|------|-----------|------------|
| +              | +           | +    | +         | 1(4.0)     |
| +              | +           | +    | -         | 0(0.00)    |
| +              | +           | -    | +         | 2(0.7)     |
| +              | +           | -    | -         | 1(0.4)     |
| +              | -           | -    | +         | 3(1.4)     |
| +              | -           | +    | -         | 1(0.4)     |
| +              | -           | -    | -         | 3(1.4)     |
| -              | -           | -    | +         | 12(4.4)    |
| -              | -           | +    | +         | 2(0.7)     |
| -              | +           | +    | +         | 2(0.7)     |
| -              | -           | +    | -         | 3(1.4)     |
| -              | +           | +    | -         | 1(0.4)     |
| -              | -           | -    | -         | 1(0.4)     |

**Table 4:** Comparison of laboratory findings in patients with confirmed dengue fever

|                   | Microscopy |     |       | Culture |     |       |
|-------------------|------------|-----|-------|---------|-----|-------|
|                   | +          | -   | Total | +       | -   | Total |
| Microscopy        | 2          | 11  | 103   | 1       | 102 | 103   |
| Culture           | 3          | 0   | 103   | 3       | 100 | 103   |
| Total             | 101        | 101 | 202   | 100     | 102 | 202   |
| Agreement         | 1.1%       | 0%  | 0%    | 0.00%   | 0%  | 0%    |
| Disagreement      | 0.1%       | 0%  | 0%    | 0.12%   | 0%  | 0%    |
| Overall agreement | 0.3%       | 0%  | 0%    | 0.12%   | 0%  | 0%    |
| N                 | 0%         | 0%  | 0%    | 0%      | 0%  | 0%    |

Discussion

... d f ... d ... d ...  
... d ... b ...  
f ... d ...  
... b ... d ...  
d ... d f ... d ... d  
... d ... d ... f  
... f ... d d ... f ... N  
... f d ...  
... d ... d ... f ...  
b ... f ... d ... d ...  
... f ... b ... f ... d ... b ...  
... d ... 3.2%, f ... d b ...  
(.2%), f ... (.%) d ... (34. %).  
... d ... d ...  
... b ... f ... %)  
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(%. %), ... (.2 %), ... (43. %),  
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... (2-.33,  
0.02). ... f ... d ...  
... , ... d ...  
... d ... d ...  
... d ... f ... b ...  
... f ... b ... d ... f ...  
... d ... d ...  
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... f ... f ... (., %0%).  
... f ... f ... f ...  
... d ... d d ... f ...  
... b ... d ... 13.

b ... d ... f 101. ...  
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... f ... d ... b ...  
... b ... d ...  
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NO ... d ... Of  
... d ...  
... d ...  
b ... d ... d ...  
... M. tuberculosis.  
... d ... d ... b ... f  
... b ... b ... d ...  
... f ... b ...  
d ... f f ... f ...  
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14.

101 ... M.  
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... d ... d ... b ...  
... f ...  
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... f ...  
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... d b ... d ... f ... d ...  
... b ... d ... d db ...  
... b ... d ... d ... Of  
... 0 ... f ... d ...  
b ... b ... d ... d ...  
... d ... f ...  
... b ... d ... f ... f ...  
... d ... b ... f ... d ...

... d ...  
... d d ... f ... % ...  
... 4.12%, ... f ... 4.1% ...  
... f ... % ... f ...  
f ... 3%, d ... ff ...  
... % ...  
... d ... f ...  
... ff ... d ... f ...  
f ... d ... f ...  
... f ... f ...  
... f ... d ... d ...  
... 1.0 %, ... .11%, ...  
f ... .32%, ... f ...  
... 0.1%, ... ff ... .1%, d ...  
... ff ... 10% ...  
... f ...  
... d ... d f ...  
... b ... d ...  
... 100% ( / ) ... d ... 4.2%  
(N /104) ... d ... d ...  
... d ... d ...  
... b ... d ... b ...  
... d ... f ...  
... b ... d ... N ... d ...  
... d ...  
... f ...  
... b ... d ... M.  
tuberculosis .

et al. ... d ...  
... N ... f ... d ... f ...  
... d ... d ... d ...  
... f ... d ...  
... % d ...  
... %  
... %1.  
... d ... f ...

