



HOKKAIDO UNIVERSITY

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Author(s)	Bhagwan, Maharjan
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学位論文内容の要旨

博士の専攻分野の名称：博士（獣医学）

氏名： Maharjan Bhagwan

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Establishment of the diagnostic system of tuberculosis feasible in
developing countries

（開発途上国で実施可能な結核診断システムの確立）

OMNIgene SPUTUM (OMS) is suitable solution for transporting samples from peripheral sites to central laboratory without cold chain and OMS treated smear and culture results were better than standard of care method and Methyl Green (MeG) dry lamp result were comparable to gold standard culture test.

In Chapter I, the novel sputum transport solution; OMS was examined to show higher case detection, minimized laboratory procedures, eliminated cold chain and can undergo multiday ambient-temperature for transporting TB suspected samples from periphery to central laboratory for smear and culture testing. It substantially helps to mitigate key challenges associated with traditional sputum transport of national tuberculosis control program of Nepal. However, future investigations with larger sample sizes seemed to be valuable. In addition, testing via liquid culture, testing smear-negative sputa with extended transport, and analysis of cost savings also seemed to be necessary.

In Chapter II, OMS-stabilized sputum for long term transport and GeneXpert MTB/RIF testing were evaluated in Nepal. The research findings suggested that sputum sample can be transported in OMS for at least 7 days without cold chain and still yield smear and GeneXpert MTB/RIF result that are concordant with sample transported with cold chain. A slightly greater proportion of smear-negative but GeneXpert MTB/RIF

-positive samples were detected after OMS treatment requires further investigation with larger sample sizes. This could help determine whether adding OMS to sputum samples can increase the sensitivity of the GeneXpert MTB/RIF assay by allowing more smear-negative samples (i.e., low-positives that may be graded smear-negative) to be detected as MTB in the GeneXpert MTB/RIF assay.

In Chapter III, a simple visual methyl green (MeG) based dry loop-mediated isothermal amplification (LAMP) method for early detection of MTB from clinical samples was developed. MeG was identified as a novel dye for simple and visual detection of LAMP reactions. Additionally, MeG-based MTB-LAMP visual detection system was simplified by preparing dried reagents and validated to demonstrate its potential for the diagnosis of TB in Nepal and potentially other developing countries. Further improvement of the dry MeG-based MTB-LAMP system will help to develop it as an effective POC test.

In summary, this study showed that the combination of novel sputum transport solution for increasing detection rate, OMS-stabilized sputum for long term transport and Xpert MTB/RIF testing, and the direct detection of MTB in clinical samples by dry MeG-based MTB-LAMP method can make diagnosis of TB in developing country feasible.