

# Evaluation of OMNIgene-SPUTUM as a sputum stabilizer for transportation to referral laboratories

## Study rationale

An effective sputum transportation system is all the more essential to improve tuberculosis (TB) diagnosis and to ensure proper treatment monitoring of multidrug resistant (MDR)-TB patients.

## Background

An estimated 90,000 cases (34% of the total estimated cases) are missed in Bangladesh annually, which is further deteriorated by lack of improved diagnostics at the peripheral level. Currently, Xpert MTB/RIF assay (Xpert), the highly sensitive laboratory diagnostic, is limited to about one-fifth of the existing microscopy centers. Moreover, MDR-TB patients continuing treatment at the community levels require submitting sputum specimen for mycobacterial culture testing throughout their treatment cycle, which is available only in divisional headquarters. Sputum transportation mechanism can ensure universal access of these lab investigations from remote areas. But, inappropriate transportation and storage reduce yield of *M. tuberculosis* (MTB), which hinders TB diagnosis and, proper treatment monitoring of MDR-TB patients. OMNIgene-SPUTUM (OM-S) is a sputum transportation reagent that keeps the MTB viable for up to 8 days at as high as 40°C temperature. Several studies have demonstrated the effectiveness of OM-S in improved TB detection using different laboratory assays (smear microscopy, culture and Xpert) with less contamination and, can eliminate NALC/NaOH decontamination process. Thus, it can reduce the cost and simplify the laboratory work flow. Government and National TB Control Program (NTP) can overcome many hurdles by integrating one such beneficial tool in the laboratory system.

The major objectives of the study were to:

1. evaluate the effect of OM-S as a sputum stabilizer for transportation to referral laboratories;
2. increase the detection of *M. tuberculosis* using OM-S reagent in sputum specimen;
3. compare the contamination rate of OM-S mixed sputum specimen to that of sputum specimen without OM-S; and
4. identify the operational challenges using OM-S reagent for sputum transportation.

Secondary objectives of the study were to:

1. analyze the transportation cost with and without OM-S reagent in sputum specimen; and
2. compare the Xpert results of both centrifuged and non-centrifuged OM-S mixed sputum specimens for a subset of patients.

## Methodology

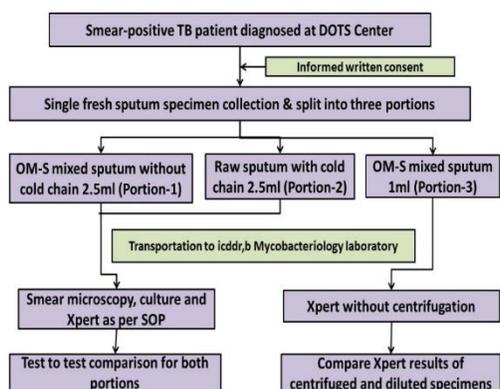
### Study sites

- Narayanganj 300 Bedded Hospital, Keraniganj, Savar and Dhamrai Upazilla Health Complexes (same day transportation to evaluate effect of OM-S on sputum during transportation)
- Chest Disease Clinic, Chattogram (distant transportation by local courier service to investigate the performance of OM-S for increased MTB detection)

# Research brief

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### Study activities



### Inclusion criteria

Smear-positive PTB patients-

- Diagnosed at the DOTS centers in the selected health facilities
- More than 11 years old
- Can expectorate adequate ( $\geq 5$  mL) sputum specimen
- Consented and assented (where applicable) to be enrolled

Figure 1: Study Activities

### Other activities:

- Field and laboratory staff involved in study were interviewed regarding operational challenges for using OM-S reagent for instance, difficulty in using OM-S in sputum specimens at field sites, sputum transportation etc.
- Cost of sputum transportation and relevant information have been recorded for cost analysis

Calculated sample size: Smear positive TB patients, n=425. Duration: January-December 2019.

### Major findings

1. For same day transportation: All laboratory test results were comparable in both “Raw” and “OM-S mixed” portions indicating **OM-S does not have any effect while mixing with sputum specimen**.
2. For distant transportation: Positivity of culture was increased by 3% in OM-S mixed portion.
3. Primary contamination rate of culture was significantly lower in OM-S mixed specimen for distant transportation although positivity rate was not significantly increased.
4. The median time required for culture positivity for both “OM-S mixed” and “raw” sputum was 35 days and this was similar in both same day transportation and distant transportation arms.
5. Xpert MTB/RIF assay results were comparable in OM-S mixed sputum specimen irrespective of centrifugation.
6. OM-S was found to be user-friendly at field sites.

### Conclusion

OM-S is user friendly and can be useful to transport sputum from point-of-care to reference laboratories to perform Xpert and, culture with lower contamination rate to follow up MDR-TB patients' treatment monitoring.

### Recommendations

The study recommends to conduct large scale studies including remote areas to validate the study findings and, to assess the cost effectiveness in wide range use of this reagent.

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