

## How can I use OMNIGene®•SPUTUM?

### Use Case 2: Reflex testing: Only one sample collection is needed

Sample collection regimes for TB testing vary widely among programs. Many national TB programs have adopted the World Health Organization's current recommendation of collecting two sputum samples per patient; however, some countries are still attempting to collect three specimens. The rationale for multiple collections is predicated on multiple factors, including test failure rates, test location and test sensitivity.

There are several purposes behind multiple collections:

1. **Backup:** At least one sample has been kept as backup in case a culture or other test fails due to contamination (i.e., producing a non-diagnostic result).
2. **Multiple test locations:** Separate samples can be transported to different laboratories within a program's referral network (e.g., to a GeneXpert® hub as well as to a separate drug susceptibility testing site).
3. **Algorithms:** Some countries' diagnostic algorithms call for duplicate smear microscopy on separate samples due to low sensitivity for this test.

However, it can be very difficult to collect more than one high quality specimen from a TB patient due to timing, patient retention and patient adherence to the protocol. Some countries that require two specimens per patient as part of their national algorithm have **less than 25% adherence** to this protocol because of the complexities of collecting two samples per patient. Expense is another consideration as, compared to a single specimen, it is costlier to ship duplicate or triplicate samples by cold chain and refrigerate them during storage.

### A new solution: Collect and test with just one OMNIGene•SPUTUM-treated sample

Using OMNIGene•SPUTUM enables the collection of only one sputum sample from each patient and addresses a range of important issues:

- Stabilizes and standardizes sputum samples.
- Decontaminates sputum effectively, thus reducing contamination rates and avoiding the need for repeat collection (or the need to store duplicate/triplicate backup samples) to obtain a valid culture result.
- Maintains viable *Mycobacterium tuberculosis* when samples are transported or stored at ambient temperature (up to 40°C) for up to 8 days.
- Compatible with all forms of TB diagnostic testing: smear microscopy, solid and MGIT™ culture, Xpert MTB/RIF assay (sediment and direct expectorated sputum protocols), Hain Lifescience line probe assays, and other molecular tests.
- OMNIGene•SPUTUM-treated specimens can be tested directly with the Xpert MTB/RIF assay:
  - An aliquot can be tested directly at a GeneXpert hub that has no other laboratory capacity (i.e., no centrifuge, no culture facility).
  - Once the result is known (see *Considerations* section below), the remaining unprocessed volume can be transported at ambient temperature (within 8 days' total hold time after adding OMNIGene•SPUTUM) to a culture laboratory or other site, depending on the network's sample workflow.
- One processed (centrifuged) OMNIGene•SPUTUM-treated sample can cover all tests:
  - The re-suspended sediment can be aliquoted to perform all tests in an algorithm.
  - An aliquot can even be archived (frozen long term at -20°C or -80°C) for repeat or future testing should it be needed.
- No ambiguity related to discrepant results between separate or split samples from the same patient.

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## Considerations:

**Reality and practicality** – If a program algorithm requires two sputum samples per patient, but this is not realistically possible/sustainable, then collecting just one OMNIgene•SPUTUM-treated sample is a better option. Once OMNIgene•SPUTUM is added, the sample can be transported without cold chain for up to 8 days, which can make shipping within a referral network easier and less costly. Importantly, OMNIgene•SPUTUM retains *Mycobacterium tuberculosis* viability and does not interfere with any current or foreseeable test platforms, including smear microscopy, Xpert MTB/RIF assay, solid and MGIT culture, Hain Lifescience line probe assays and other molecular testing. A single OMNIgene•SPUTUM-treated sample can be used to run all required TB diagnostic tests, and a volume can be archived (frozen long term at -20°C or -80°C) should repeat or additional testing be needed.

### **Screen with Xpert to obtain higher-confidence results and maximize investment** –

Using OMNIgene•SPUTUM transport reagent can help programs obtain more accurate test results and can even eliminate the need for smear microscopy. The Xpert MTB/RIF assay is a very good diagnostic test for screening purposes, and the results enable more rapid and appropriate treatment for patients. In contrast, smear microscopy has low sensitivity and specificity, and tells nothing about antibiotic resistance. While the cost of individual smear tests is low, the cumulative resources devoted to this method globally are great. In many settings, these resources could be better directed towards more effective testing methods.

OMNIgene•SPUTUM introduces flexibility into sample transport and laboratory scenarios because specimens no longer require refrigeration/cold chain (maximum 8 days at 4°C to 40°C) and remain testable with all TB diagnostic methods, including culture. Combining the use of OMNIgene•SPUTUM transport reagent with GeneXpert hubs (or other molecular test facilities for screening) offers TB programs valuable new options. Establishing Xpert testing as the initial (screening) test to be performed can achieve higher quality results faster, and can help countries capitalize on the significant investments they have made in purchasing GeneXpert machines. Samples in OMNIgene•SPUTUM can be transported without cold chain to a GeneXpert hub (or collected at the hub site and held at ambient/room temperature) and have the Xpert MTB/RIF assay performed as the exclusive first-line test (i.e., no smear microscopy). The remaining sample can be held at room temperature during the wait for the Xpert test result. Once the Xpert result is known, the remaining sample portion can be transported and tested elsewhere in the referral network as required (within the 8-day maximum interval after addition of OMNIgene•SPUTUM), ensuring seamless sample management and easy linkages between tests, samples and patients.

## Example scenario

When an OMNIgene•SPUTUM-treated sample is collected at, or transferred to, a GeneXpert hub in the first stage of sample workflow, the technician removes an aliquot of the sample and runs the Xpert MTB/RIF assay as the initial screening test (i.e., adds the manufacturer's SR buffer, incubates and then loads the sample into a cartridge for testing, all per the assay's procedure for direct testing of expectorated sputum). The remainder of the OMNIgene•SPUTUM-treated sample is held at room temperature until the Xpert result is known. Depending on the testing algorithm being followed, the remaining sample portion can then be reflexed for additional testing and/or transported to a reference laboratory for confirmatory testing.

Note that OMNIgene•SPUTUM keeps *Mycobacterium tuberculosis* viable at ambient temperature (4°C to 40°C) for up to 8 days. Because the sample is completely liquefied by the reagent (i.e., it is homogenous), additional aliquots of the sample can be transported for follow-up testing at other laboratories.

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