How can I use OMNIgene®•SPUTUM?

Use Case 4: Reflex testing: Microscopy centre with or without GeneXpert® centrifuge

As explained in Reflex Testing Use Case 2, it is very difficult to collect more than one quality specimen from a TB patient during a single visit. Even some countries that require two specimens per patient as part of their national algorithm have documented less than 25% adherence to this protocol. The rationale for multiple collections is predicated on multiple factors, including test failure rates, test location, test sensitivity and sample preparation methods that are not compatible across all diagnostic assays. Cost is another consideration, as compared to a single specimen it is more expensive to ship duplicate or triplicate samples by cold chain and refrigerate them during storage.

There is a strong case to be made for collecting and testing from a single OMNIgene•SPUTUM-treated sputum sample because of the flexibility, transport and testing advantages this reagent offers:

- Stabilizes and standardizes sputum samples.
- Decontaminates sputum effectively, thus reducing contamination rates and avoiding repeat collection (or the need to store duplicate/triplicate backup samples) to obtain a valid culture result.
- Maintains viable Mycobacterium tuberculosis at 4°C to 40°C for 8 days.
- Compatible with all types of TB diagnostic tests.
- OMNIgene•SPUTUM-treated specimens can be tested directly in 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), after which the sample can be transported on to a culture laboratory or other site for testing as needed.
- One OMNIgene•SPUTUM-treated sample can cover all tests; the re-suspended sediment can be aliquoted to perform all tests in an algorithm.
- Since all diagnostics are run on a single sample, there is no ambiguity related to discrepant results between separate or split samples from the same patient.

How to manage sputum samples at a smear microscopy centre with or without GeneXpert

When a microscopy centre receives a sputum sample for TB testing, a technician usually takes some of the raw specimen and makes a “direct smear.” However, if smear is the only test that can be done at a microscopy site and samples will be transported to another location for confirmatory testing, then adding OMNIgene•SPUTUM offers significant advantages. This reagent enables the user to safeguard sample quality during transport by decontaminating and maintaining viable Mycobacterium tuberculosis without cold chain for up to 8 days. This is crucial to allow the sample to be transported or stored/batched for reflex testing at other locations in the referral network, and to help ensure that useable diagnostic results (e.g., no culture contamination) are obtained at each testing location.

As such, options for managing raw sputum samples at a microscopy centre are described below.

Option 1. When there is no centrifuge present and smear is the only test available:

Make a direct smear from the raw sputum sample upon arrival, then add OMNIgene•SPUTUM to the sample prior to transporting elsewhere in network for further testing. Alternatively, OMNIgene•SPUTUM can be added to the sputum sample and smear microscopy can then be performed by removing an aliquot and following your standard operating procedure for staining. Preliminary evidence indicates that OMNIgene•SPUTUM does not interfere with Ziehl-Neelsen or Kinyoun staining; however, this has not been extensively tested. If you are interested in these methods, contact us for more information.

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**Option 2. When GeneXpert is present/absent:**

Perform smear staining following your standard operating procedure. See Option 1 for options.

- **If no GeneXpert machine or culture facilities are available on site,** transport OMNIgene•SPUTUM-treated samples to subsequent testing facilities (transport 8 days maximum at 4°C to 40°C).
- **If a GeneXpert machine is present,** remove an aliquot of OMNIgene•SPUTUM-treated sputum and add Cepheid’s SR buffer directly to the sample. Follow the standard operating procedure for the “Expectorated Sputum” method in the Xpert MTB/RIF assay.

**Option 3. When a centrifuge is present:**

- **Treat samples with OMNIgene•SPUTUM and centrifuge to form a sediment.** Follow the OMNIgene•SPUTUM protocol to spin, remove supernatant, and re-suspend the sediment in phosphate-buffered saline (PBS) or sterile water. Follow the “Sputum Sediment” protocol for the Xpert MTB/RIF assay.
- **To transport a concentrated sample (sediment) for testing at another laboratory,** aliquots in PBS must be transferred cold (at 4°C).