

## How can I use OMNIGene®•SPUTUM?

### Use Case 7: Supporting clinical trials (drugs, vaccines, other clinical candidates)

Clinical trials for TB vaccines, drugs and other clinical candidates require large-scale studies that involve thousands of participants. A clinical trial for a TB vaccine requires a prevalence study in the population of interest (i.e., a population where TB is known to be circulating and people are being exposed) in order to determine the cohort required to test a new vaccine efficacy. Testing the efficacy of a new antibiotic for multidrug-resistant TB (MDR-TB) requires that the rate of MDR-TB within the region be well understood and characterized prior to enrolling participants in the clinical trial.

### OMNIGene•SPUTUM solves specific challenges of clinical trials

**Problems:** Prevalence and drug surveillance studies for clinical trials are geographically extensive, demand high-volume sampling and testing, and can be logistically challenging and costly. The large numbers of raw sputum samples that need to be shipped typically means paying for multiple daily courier trips, as well as the costs associated with maintaining cold chain during transport. Further, the laboratory is typically swamped with sample numbers that greatly exceed its regular daily or weekly workload, and often staffing needs to be increased (i.e., shifts added) to handle this. Problems with culture contamination (i.e., the resultant need for additional sampling and testing), frequent courier trips, cold chain transport and staffing inefficiencies can all translate to high costs for these studies.

**Solution:** OMNIGene•SPUTUM addresses all these challenges and facilitates cost-management in multiple ways. Adding this reagent to sputum, decontaminates the specimen, reduces contamination rates, and makes it possible to delay testing by up to 8 days without refrigeration. It also allows samples to be batched prior to testing, and avoids labour inefficiencies associated with the time constraints of the NaOH/NALC decontamination method. The methods for adding OMNIGene•SPUTUM are simple and specimens can be treated either at the collection site or upon arrival at the laboratory.

### What are the outcomes?

- Substantially lower contamination rates.
- Reduced costs due to fewer courier pick-ups/deliveries (samples can be held/batched at temperatures between 4°C and 40°C).
- Reduced costs due to elimination of cold chain shipping.
- More cost-effective staff scheduling and shift planning (batching enables laboratory managers to predict when additional shifts are needed, optimize the size of test runs and maximize technician time).
- Faster laboratory turnaround times (batching helps optimize and speed testing).
- More efficient use of laboratory resources (e.g., fewer biosafety hoods needed, less hood time required, fewer MGIT tube purchases for repeat testing).
- More efficient population survey and clinical trial overall (fewer repeated tests are needed to understand the impact of the vaccine or drug in the population).

Some DNA Genotek products may not be available in all geographic regions.

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All DNA Genotek protocols, white papers and application notes, are available in the support section of our website at [www.dnagenotek.com](http://www.dnagenotek.com).