How can I use OMNIgene®•SPUTUM?

Use Case 6: Supporting national surveillance studies (drug resistance studies, prevalence studies)

National surveillance studies include drug resistance investigations, prevalence studies, and other large-scale studies that are essential to national and global policy-making, as well as operational (programmatic) research and more. These studies are geographically extensive and require thousands of samples to be collected, transported and tested. Countries face significant challenges related to sample collection, and maintaining sample quality during different durations and conditions of transport to the designated laboratory/ies. In addition, there are staffing and logistical issues with the volumes of laboratory processing and testing required. As a result, long delays in testing due to limited resource availability can lead to high culture contamination rates and overall test failures.

OMNIgene•SPUTUM solves specific challenges in large-scale surveillance studies

Problems: National surveillance studies deliver thousands of samples to the clinical laboratory, and the facility must manage this substantial extra volume on top of regular weekly work. Capacity for this additional processing and testing is a major issue; arriving samples are frequently left sitting for long periods and contamination rates can be as high as 50%. In order for the study to accurately represent the national TB infection prevalence, a large cohort must be analyzed. The associated large losses from contamination mean that investigators must expend significant additional time, effort and cost to sample even more individuals in the population.

In other words, without the number of diagnostic results dictated by the study design, the findings are not informative at the national or international level. The extra effort to collect, test and analyze thousands of additional samples to make up for the losses can add months of research time (i.e., national TB surveys often take 18 months). These factors directly affect each country’s ability to deliver its prevalence and surveillance data to the World Health Organization on an annual basis, which leads to international concern about delays in data reporting.

Solution: OMNIgene•SPUTUM addresses all the challenges described above. Adding this reagent to sputa decontaminates the specimens and reduces contamination rates. This stabilizing agent also allows delayed testing for up to 8 days without need for refrigeration and allows samples to be batched. The methods for adding OMNIgene•SPUTUM are simple and specimens can be treated either at the collection site or upon arrival at a laboratory.

OMNIgene•SPUTUM can be added to raw sputum at point-of-collection or when the sample arrives at the laboratory. Optimizing and standardizing all samples with this reagent enables samples to be batched such that managers can streamline and organize the work. Treating samples with OMNIgene•SPUTUM gives a laboratory manager an 8-day window for testing, which translates to greater flexibility needed to control scheduling. The manager can establish the desired distribution of processing/testing over workdays, throughout each week and across weeks/weekends, and can fine-tune staffing capacity (even add shifts as needed) to handle large workloads. All this translates to significantly more efficient use of staff and resources with improved data outcomes during national prevalence and surveillance studies.

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What are the outcomes?

- Substantially lower contamination rates.
- 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 use of national resources (fewer additional collections/tests needed, study completed on time).
- Faster laboratory turnaround times (batching helps optimize and speed testing).
- Less labour-intensive work, better scheduling and shift planning (technician time is maximized).
- Less costly (fewer additional samples collected and tested).
- More efficient national survey overall.
- Better national surveillance data generated (greater understanding of national status in all aspects of TB).
- Ability to report back to the World Health Organization in a timely manner.