

OM-SPD

Smear Culture

OPTIMIZE • SCALE • SIMPLIFY • MAXIMIZE

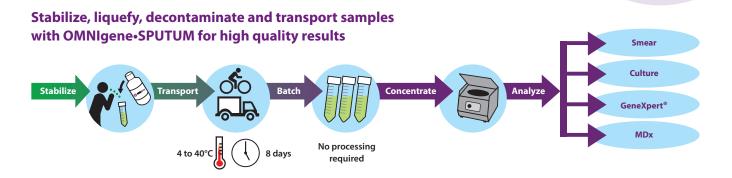
Maintain *Mycobacterium tuberculosis* (MTb) viability while liquefying and decontaminating sputum samples during transport

OMNIgene[®]•SPUTUM is a non-toxic and highly stable reagent that liquefies and decontaminates sputum samples at the point-of-collection or in the lab. MTb viability is maintained for 8 days at ambient temperatures ranging from 4°C to 40°C. Optimized samples are compatible with all routine TB tests, enable cost-effective sample transport, and simplify laboratory workflows while eliminating the need for NaOH/NALC.



Product catalog #: OM-SPD-250 and OM-SPD-1000

For more information contact info@dnagenotek.com



Optimize high quality samples	Scale	Simplify	Maximize centralized testing
 Stabilize, liquefy and decontaminate sample at point-of-collection Eliminate samples lost due to putrefaction 	 Eliminate cost and complexity of cold chain shipping Collect and transport more samples at lower cost 	 Simplify processing and batching sputum in the lab Eliminate cost and time of NaOH/NALC Minimize contamination and cross contamination 	 Optimize sample for all diagnostic algorithms Enable differential diagnostic testing

For In Vitro Diagnostic Use

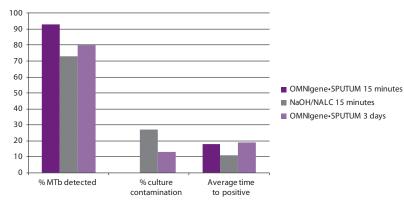
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Figure 1: Performance comparison of OMNIgene•SPUTUM and NaOH/NALC in MGIT culture

OMNIgene-SPUTUM improves detection of MTb positive samples in MGIT culture, reduces culture contamination rates and allows for long-term holds at room temperature.



"There is a growing need to dramatically expand and strengthen TB laboratory services, including increasing access to high quality microscopy, culture, drug susceptibility testing (DST) and new diagnostics."

> Stop TB Partnership, Global Laboratory Initiative

Methods: Sputum samples (n = 15) were collected and split manually into 3 aliquots. One aliquot was immediately treated with OMNIgene-SPUTUM and held for 15 minutes at room temperature. A second aliquot was immediately treated with NaOH/NALC and held for 15 minutes at room temperature. The third aliquot was immediately treated with OMNIgene-SPUTUM and held for 3 days at room temperature. At the end of the designated hold time, sediments were formed by centrifugation. Sediments were evaluated by smear microscopy, Cepheid GeneXpert and MGIT culture. For all samples, smear and GeneXpert were comparable, with minor variations attributable to manual splitting of sputum samples prior to liquefaction (data available upon request).

Product attributes	OMNIgene•SPUTUM	NaOH/NALC
Maintains MTb viability	8 days	15 minutes
Shelf-life	1 year	12-18 hours
Bulk reagent	Y	Y
Off-the-shelf reagent	Y	N
Non-toxic	Y	N
Does not require quality control	Y	N
Stabilizes sample at point-of-collection	Y	N
Liquefies and decontaminates	Y	Y
Stabilizes DNA for differential diagnostic testing	Y	N
Easy-to-use	Y	N
Transport at ambient temperature	Y	N
Simplifies laboratory workflows	Y	N
Improves laboratory worker safety	Y	N
Reduces routine laboratory workload	Y	N

Table 1: Product comparison: sample optimization, sputum transport and overall ease-of-use

OMNIgene•SPUTUM is compatible with the following sputum types: expectorated, induced, aspirated, bronchial lavages and washes.

OMNIgene•SPUTUM is available in multiple size formats (250 mL and 1L).

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

*OMNIgene is a registered trademark of DNA Genotek Inc. All other brands and names contained herein are the property of their respective owners. Patent (www.dnagenotek.com/legalnotices)

Superior samples • Proven performance

DNA GENOTEK

Compatible with all testing methods. 100% concordance with NaOH/NALC for all tests.