

Maximizing centralized testing models and GeneXpert® hubs with OMNIGENE•SPUTUM

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Challenge

The Cepheid® GeneXpert® system and molecular diagnostics are changing the way that Mycobacterium tuberculosis (MTb) infections are diagnosed and treated. If implemented properly, molecular testing is faster than culture and more sensitive than smear microscopy. With only an estimated 60% of active tuberculosis cases being diagnosed and approximately 3 million cases missed each year, there is an urgent need to increase access to GeneXpert and molecular testing hubs to maximize the efficiency of current testing infrastructure and diagnose more cases.

Solution

OMNIGENE•SPUTUM offers a flexible approach to tuberculosis sample management and shipping that can scale centralized testing models and provide optimized high quality sputum samples.

Adding this reagent has multiple benefits: reduces putrefaction, stabilizes samples, decreases culture contamination rates, reduces costs and simplifies workflows at the laboratory. Samples optimized with OMNIGENE•SPUTUM are compatible with routine smear, culture and molecular methods, including Cepheid GeneXpert.

Technical notes

OMNIGENE•SPUTUM is a stable, non-toxic reagent that liquefies and decontaminates sputum while preserving MTb viability for at least 8 days at 4°C–40°C. The product is added to samples at approximately 1:1 ratio and can be used at point-of-collection (so samples can be shipped at ambient temperature) or as a lab-added liquefaction/decontamination reagent.

Results

Sputum sediments	Positivity	(n)	Method	% samples with MTb detected	Rifampicin	
					Res	Sens
High	5		OMNIGENE•SPUTUM	100%	2	3
			Cepheid protocol H.1		2	3
Mid	9		OMNIGENE•SPUTUM	89%	0	8
			Cepheid protocol H.1		0	8
Low	10		OMNIGENE•SPUTUM	80%	2	6
			Cepheid protocol H.1	90%	1	8

Expectorated sputum	Positivity	(n)	Method	% samples with MTb detected	Rifampicin	
					Res	Sens
High	10		OMNIGENE•SPUTUM	100%	1	9
			Cepheid protocol H.2		1	9
Mid	10		OMNIGENE•SPUTUM	100%	0	10
			Cepheid protocol H.2		0	10
Low	10		OMNIGENE•SPUTUM	80%	0	8
			Cepheid protocol H.2		0	8

Table 1: Compatibility with Cepheid GeneXpert methods.

Conclusion

Data demonstrate compatibility of OMNIGENE•SPUTUM optimized samples with Cepheid GeneXpert package insert methods.

The ability to ship OMNIGENE•SPUTUM optimized samples at ambient temperature can increase access to GeneXpert tests. This reagent allows TB control programs to implement sample batching and increase use and efficiency of centralized testing models.

Compatibility: OMNIGENE•SPUTUM is compatible with the Cepheid GeneXpert MTB/RIF assay. Data generated at a third-party TB reference laboratory shows concordance with both package insert methods for sediments and expectorated sputum.

