

How can I use OMNIGene®•SPUTUM? Frequently Asked Questions

What if my setting or transport system is different from scenarios mentioned in the use cases?

OMNIGene•SPUTUM can be used flexibly and is not limited to the scenarios listed; it offers benefits in a wide variety of settings. Two of the many examples are below.

Example 1: Samples may be obtained at a remote collection site that is not a laboratory and the reagent can be added at the time of collection using one of several simple methods. Once mixed with OMNIGene•SPUTUM, samples can be batched and transported without cold chain for up to 8 days.

Example 2: Samples may arrive at a laboratory untreated or may be collected at a laboratory. Even when samples don't require transport, adding OMNIGene•SPUTUM at the laboratory is still very advantageous. Doing this eliminates all the time constraints and routine laboratory work associated with the NaOH/NALC decontamination steps.

What if I store OMNIGene•SPUTUM-treated samples at 4°C or frozen?

If OMNIGene•SPUTUM-treated sputa are held at 4°C or frozen (-20°C to -80°C), they need to be warmed to room temperature for at least 20 minutes prior to centrifugation. Centrifuging samples while still cold will result in poorly formed sediments and this can result in loss of sediment material when pouring off the supernatant.

What if my Xpert site is not Biosafety Level 2?

Care should always be taken when handling sputum that is suspected to contain *Mycobacterium tuberculosis* and appropriate safety precautions are critical for protecting laboratory testing staff from potential exposures. OMNIGene•SPUTUM-treated samples can retain viable *Mycobacterium* bacilli for at least 8 days post-collection. To run a sample in the direct "Expectorated Sputum" procedure of the Xpert MTB/RIF assay, the cap of the sample container must be opened to add Cepheid's SR buffer as per the protocol. The process of adding SR buffer to an OMNIGene•SPUTUM-treated sputum sample poses no greater hazards or risks than testing staff would encounter working with untreated sputum.

What if my diagnostic algorithm or workflow is different from the example scenario?

Any algorithm or workflow can be accommodated when OMNIGene•SPUTUM is used. Once an OMNIGene•SPUTUM-treated sample is processed, the sediment should be re-suspended in the smallest volume of phosphate buffered saline or sterile water that will accommodate all the desired tests. This volume can then be divided/aliquoted to cover all the tests that are needed. As well, a volume can be reserved and stored in case repeat testing or additional diagnostics are required.

Must all tests be run at the same time? Can I reserve a sediment for later testing or repeat testing if needed?

Once a sediment has been re-suspended in sterile buffer, it is equivalent to sediments obtained after any other decontamination/liquefaction procedure, such as NaOH/NALC. Storage of sediments should follow the standard operating procedures established by your laboratory.

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