How can I use OMNIgene®•SPUTUM?

Use Case 3: Reflex testing: How to run multiple tests from one sample

A major benefit of adding OMNIgene•SPUTUM to a sputum specimen is that the reagent's liquefying and decontaminating properties preserve and stabilize the specimen. The sample can then be used in all downstream testing. In addition, unlike the NaOH/NALC method, a sample transported and stored in OMNIgene•SPUTUM does not have to be processed immediately; it can be held unrefrigerated at temperatures up to 40°C for a maximum of 8 days.

How to use an OMNIgene•SPUTUM-treated sample for multiple tests:

1. Collect the sample
   - Patient produces sputum sample into standard collection cup or tube.
   - Visually estimate the volume of sputum collected.
   - Add an approximately equal volume of OMNIgene•SPUTUM.
   - Recap the sample container tightly.
   - Invert 10 times to mix.
   - Incubate specimen at room temperature (15-25°C) for at least 30 minutes (periodic re-mixing will facilitate liquefaction).
   - Samples may be held between 4°C and 40°C for up to 8 days.

Methods for adding OMNIgene•SPUTUM are simple, see Instructions For Use (ROW) and Instructions For Use (USA).

2. Process the sample
   - Vortex 15-20 seconds or invert 10-20 times to mix.
   - Centrifuge at 3,800 × g for 20 minutes to obtain a sediment.
   - Gently pour off supernatant.
   - Re-suspend sediment in a volume of sterile phosphate-buffered saline (PBS) or sterile water that accommodates the required tests.

3. Aliquot and test per the desired workflow

The next steps can be tailored to the diagnostic algorithm of any laboratory, program or study.

Example scenario
Unprocessed samples arrive at the laboratory. The technician treats them with OMNIgene•SPUTUM as described above, allows the samples to sit at room temperature for a minimum of 30 minutes, processes them as described above, then re-suspends the sediments in 1.5 mL of PBS.

Each re-suspended sediment sample is then divided according to the system or network testing algorithm (see Figure 1):
   - 50 µL for smear microscopy and Lowenstein-Jensen solid culture.
   - 500 µL for MGIT.
   - 700 µL for molecular testing:
     - 500 µL for Cepheid Xpert MTB/RIF assay.
     - 200 µL for DNA extraction using prepIT®•MAX, then Hain Lifescience line probe assay.
Figure 1. Sample workflow in an example system scenario.

Collect
sputum sample from patient

Direct smear
(if part of program/network SOPs)

Add OMNIgene-SPUTUM
at 1:1 ratio

Transport
(no need to refrigerate or ship using cold chain)

Process
(centrifuge and re-suspend sediment)

Aliquot and test
(per program/network SOPs)

Example
50 µL for smear + solid culture
and/or
500 µL for MGIT
and/or
700 µL for molecular

500 µL for Xpert MTB/RIF assay
and/or
200 µL for DNA extraction + Hain LPA

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