



OMNigene®•SPUTUM


Reagent for optimizing TB samples

REF OM-SPD

Product handbook

The following handbook is a method for the collection and preparation of sputum samples for use in tuberculosis testing using OMNigene®•SPUTUM.

Note: TB bacteria will remain viable in the OM-SPD reagent.

 15°C ~~25°C~~

Wash with water if liquid solution comes in contact with eyes or skin. Do NOT ingest. See MSDS at www.dnagenotek.com.

Patent (www.dnagenotek.com/legalnotices)

**For research use only,
not for use in diagnostic procedures.**

Not available for clinical diagnostic use in the United States.

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CAUTION: Clinical specimens which may contain *Mycobacterium tuberculosis* (TB) should be considered infectious and handled with appropriate biosafety precautions and standards (follow local and/or federal regulations as appropriate).

Note: TB bacteria will remain viable in the OM-SPD reagent.

Intended use

OMNIgene•SPUTUM optimizing reagent (OM-SPD) is intended for liquefaction and decontamination of fresh or frozen sputum samples while preserving viable *Mycobacterium tuberculosis*.

The liquid-based reagent enables room temperature shipping and storage of sputum for up to 5 days.

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Not available for clinical diagnostic use in the United States.

Storage

OM-SPD should be stored at room temperature (15°C-25°C) and is stable until the expiration date indicated on the bottle label.

Safety information

For further safety information on OM-SPD, refer to the appropriate material safety data sheet (MSDS) available at www.dnagenotek.com.

Protocol for collecting sputum in OMNIgene-SPUTUM reagent (OM-SPD)

Reagent included

- OM-SPD

Equipment supplied by user

- Standard collection cup for sputum
- Pipettes and pipette tips

Procedure

Collection steps	Notes
1. Collect sputum into standard collection cup or tube.	
2. Visually estimate volume of sputum collected.	
3. Add approximately an equal volume of OMNIgene-SPUTUM reagent.	
4. Recap collection cup tightly.	
5. Vigorously invert specimen 10 times to mix.	
6. Incubate specimen at room temperature (15°C-25°C) for a minimum of 15 minutes. Periodic mixing (by inversion or vortexing) will facilitate liquefaction.	Highly mucoid specimens may require longer hold times or the addition of NALC to ensure full liquefaction is achieved. Samples may remain at room temperature (15°C-25°C) for up to 5 days before proceeding with the next step.

Laboratory protocol for preparation of OMNIgene•SPUTUM samples for tuberculosis diagnostics

(Smear, culture, Cepheid GeneXpert® and molecular diagnostics)

The following protocol is for the preparation of sputum samples in OMNIgene•SPUTUM (OM-SPD) optimizing reagent.

Equipment and reagent supplied by user

- Centrifuge that can accommodate 50 mL tubes and is capable of generating $3,800 \times g$
- 50 mL conical polypropylene tubes (e.g., Sarstedt #62.547.205)
- Sterile phosphate buffered saline (PBS) or sterile water
- Appropriate biosafety equipment and personal protective equipment as required by your institution and/or biosafety committee.

Procedure

Sample preparation steps	Notes
1. Vortex for 15–20 seconds or invert 10–20 times to mix.	
2. Spin OM-SPD specimen at $3,800 \times g$ for 15–20 minutes to obtain a sediment.	Transfer sample to a 50 mL conical tube if needed.
3. Gently pour off supernatant into appropriate waste container without disturbing the sediment. Do NOT discard sediment.	The sediment contains viable <i>Mycobacterium tuberculosis</i> .

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Sample preparation steps	Notes
4. Resuspend the sediment in sufficient volume of sterile phosphate buffered saline or sterile water in order to complete standard laboratory test procedures.	
5. Aliquots may be removed for: a) Smear b) Culture testing (including BBL MGIT culture system) c) Cepheid GeneXpert® MTB/RIF testing d) Molecular diagnostics	a) Follow laboratory SOPs for smear. b) Follow laboratory SOPs for culture. c) Follow manufacturer's recommended protocol for Cepheid GeneXpert® MTB/RIF d) For molecular diagnostics, follow DNA Genotek's prepIT®-MAX for TB purification protocol or other extraction systems.

Shipping

Note: TB bacteria will remain viable in OM-SPD reagent.

Samples optimized using OM-SPD reagent should be considered infectious/dangerous goods and travel as UN3373, Biological Substance, Category B.

Packaging and shipment of specimens in OM-SPD reagent must be done in accordance with local regulations and/or IATA guidelines for the shipment of biohazardous/infectious specimens.

Technical support is available Monday to Friday (9h00 to 17h00 EST):

- Toll-free (North America): 1.866.813.6354, option 6
- All other countries: 613.723.5757, option 6
- Email: support@dnagenotek.com





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.

All DNA Genotek protocols, white papers and application notes are available in the support section of our website at www.dnagenotek.com.

Label legend:

	Catalog number
	Caution, consult instructions for use
	Storage instructions
	Manufacturer

Made in Canada

 DNA Genotek Inc.

Ottawa, ON, Canada K2K 1L1

Subsidiary of OraSure Technologies, Inc.

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