OMNIgene®•SPUTUM

Reagent for optimizing TB samples

The following protocol 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 OMNIgene•SPUTUM reagent.

Intended use

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

The liquid-based reagent enables shipping and storage of sputum for 8 days between 4°C and 40°C.

Summary and explanation of reagent

OMNIgene•SPUTUM is a reagent that facilitates the collection and transport of sputum samples for use in tuberculosis testing. This product liquifies and decontaminates sputum samples while enabling ambient temperature transport for up to 8 days.

Quantity

OMNIgene•SPUTUM reagent is available in various volumes.

Examples	
Product	**Volume**
OM-SPD-50	50 mL
OM-SPD-250	250 mL
OM-SPD-1000	1000 mL

Warnings and precautions

For In Vitro Diagnostic Use

1. Clinical specimens which may contain Mycobacterium tuberculosis 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 OMNIgene•SPUTUM reagent.

2. Do NOT use after the "Use by" date indicated on the bottle label.

Storage

OMNIgene•SPUTUM should be stored at room temperature (15°C to 40°C).

Safety information

Wash with water if reagent comes in contact with eyes or skin. Do NOT ingest.

Safety data sheet (SDS) is available at www.dnagenotek.com

Specimen collection and handling

Protocol for collecting sputum with OMNIgene•SPUTUM reagent

Reagents included

- OMNIgene•SPUTUM

Equipment supplied by user

- Standard collection cup/tubes 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 30 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 between 4°C and 40°C for up to 8 days before proceeding with the next step.

CE IVD 15°C 40°C

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Protocol for specimen preparation for smear, culture, Cepheid GeneXpert® and molecular diagnostics

The following protocol is for the preparation of sputum samples in OMNIgene•SPUTUM optimizing reagent.

Equipment and reagent supplied by user

- Centrifuge that can accommodate 50 mL tubes and is capable of generating 3,800 × *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. Transfer the sample to a 50 mL conical tube (if necessary) and add PBS to the top of the tube (final volume 50 mL). Vortex for 15–20 seconds or invert 10–20 times to mix.	
2. Spin OMNIgene•SPUTUM specimen at speeds between 3,000 - 3,800 × *g* for 20 minutes to obtain a sediment.	If a compact sediment is not formed re-spin specimen at 3,800 × *g*.
3. Gently pour off supernatant into appropriate waste container without disturbing the sediment. Gently pipette off any remaining supernatant. **Do NOT discard sediment.**	Do not disturb the sediment as it contains viable *Mycobacterium tuberculosis*.
4. Resuspend the sediment in sufficient volume of sterile PBS 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) and solid culture 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 manufacturer's recommended TB DNA extraction protocols.

Shipping

Note: TB bacteria will remain viable in OMNIgene•SPUTUM reagent.

Samples optimized using OMNIgene•SPUTUM reagent should be considered infectious/dangerous goods and travel as UN3373, Biological Substance, Category B.

Packaging and shipment of specimens in OMNIgene•SPUTUM reagent must be done in accordance with local regulations and/or IATA guidelines for the shipment of biohazardous/infectious specimens.

Disposal

Disposal of this product should comply with any local or regional regulations.

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

- Toll-free (North America): 1.866.813.6354, option 6
- All other countries: +1.613.723.5757, option 6
- Email: support@dnagenotek.com

Label legend:

	Use by
CE	CE marking
IVD	In vitro diagnostic medical device
REF	Catalog number
LOT	Lot number
15°C 40°C	Storage instructions
	Manufacturer
EC REP	Authorized representative

EC REP Emergo Europe, Prinsessegracht 20
2514 AP The Hague, The Netherlands

DNA Genotek Inc.
3000 - 500 Palladium Drive
Ottawa, ON, Canada K2V 1C2
Subsidiary of OraSure Technologies, Inc.

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