

Snap N' Digest

Snap N' Digest

Manufacturer/Supplier:
Scientific Device Laboratory
411 Jarvis Ave, Des Plaines, IL 60018 USA
General and Technical Information
Phone Number: 847-803-9495
Website: www.scientificdevice.com

Intended Use:

Snap N' Digest is made to facilitate the digestion and decontamination of clinical specimens (such as: sputum, bronchial or tracheal lavage) suspected to contain mycobacteria, especially *Mycobacterium tuberculosis*.

Summary and Explanation:

Most clinical specimens that are sent to the laboratory for culture of suspected Mycobacterial infection are contaminated by rapid growing normal flora. In order to maximize the Mycobacterial yield of a clinical specimen, N -acetyl-L-cysteine (NALC) is used with the clinical specimen as a digesting, decontaminating, and mucolytic agent. NALC is effective as a digestant only in the reduced form: when oxidized to the cystine. In the reduced state the chemical acts to break disulfide bonds that are rich in mucus and ultimately to thin out the mucoid sputum. The NALC in a dry powder form is sealed in glass ampules. The NALC remains in its unreduced state and retains its potency until the ampule is broken and added to the specimen. The Sodium Hydroxide acts as a decontamination fluid destroying the host normal flora except the *Mycobacterium tuberculosis* and other species.

Principle of the Procedure:

In the SDL Snap N' Digest reagent bottle, the N -acetyl-L-cysteine (NALC) is combined with 2% Sodium Hydroxide (NaOH). When the glass ampule containing NALC is broken and mixed with NaOH-citrate solution, this mixture provides an effective digestion and decontamination for clinical specimens. Snap N' Digest solution is added in equal amounts to the clinical specimen.

Components:

Snap N' Digest in 75ml bottle or 150ml bottles (buffer packets included):
Liquid – Trisodium citrate (0.1M) 2.9% / Sodium hydroxide 2.0%
Capsule – N -acetyl-L-cysteine (NALC) 0.375grams per ampule

Warnings:

Do not use product beyond the expiration date.
Break glass ampule close to its center one time. Do not manipulate glass ampule plastic bottle may puncture from glass and injury may occur.
Do not use reagents if ampules do not appear to contain powder or if capsules are broken, missing or there is visible evidence of deterioration (e.g. reagent develops yellow color). Do not use phosphate buffer if packages are torn or unsealed..

Storage:

Store at room temperature (15°C to 30°)
Do not freeze. Do not open until ready for use.

Procedure:

Preparation of Phosphate Buffer: (note: prepare as needed) Note: Once Phosphate buffer solution is made; it should be sterilized and used immediately. If held longer, maintain sterility and refrigerate for no longer than three days.
Pour entire contents of one buffer package (included in Snap N' Digest kit) into a 500 mL flask and add 500mL deionized water.
Mix with stirring rod, then autoclave at 121°C for 15 minutes
Allow buffer to cool, use as needed

Reagent Use:

Prior to use, loosen screw-cap on the plastic bottle. Locate ampule in bottle and squeeze bottle in the upright position until ampule breaks. (Note: 75ml bottle contains one ampule to break and 150ml has two). Shake gently to dissolve the NALC. Try not to cause foaming in the bottle and avoid excessive shaking or agitation. **ONCE AMPULE IS BROKEN, USE REAGENT WITHIN 24 HOURS.**

Reagent Use (cont.):

In a biological safety hood, use an aerosol-free 50 ml centrifuge tube with screw cap. Add equal amounts of clinical specimen and activated

Snap N'Digest solution (approximately 10ml of each) to tube.
Cap centrifuge tube and mix on a Vortex until specimen is liquified. If specimen is especially viscous, add more digestant and repeat mixing.
Allow mixture to stand at room temperature for approximately 15 minutes and occasionally mix/shake tube gently.
Add sterile phosphate buffer (pH 6.8) (see section above on instructions to make buffer) to the 50 mL mark on centrifuge tube and mix. Centrifuge for 15 - 20 minutes at 3000 X g.
Decant supernatant fluid into Splash-proof discard container (Cat No. 250-252) which contains 5% phenol or an equivalent disinfectant.
Add small quantity of phosphate buffer to tube and re-suspend the sediment. Use the sediment for preparation of smears and Mycobacterial procedures and cultures.

Expected Results:

Snap N' Digest when used correctly will digest and decontaminate clinical specimens suspected to contain Mycobacteria.

Quality Control:

Use established laboratory quality control procedures for Mycobacterial specimens. Record in quality control manual.

Limitations:

No one method of digestion-decontamination is suitable for all specimens. When selecting a procedure, choose the procedure that will be less harmful to the specimen, but will reduce contamination.

Safety:

For *In vitro* diagnostic use. See SDS for additional information.
Use biosafety level 2 practices and procedures when preparing specimens that might contain mycobacteria.
Reagents contain strong alkali and can cause burns.
Gloves/eye/face protection must be worn.
NaOH is irritating to eyes and skin. In case of eye or skin contact, flush immediately with copious amounts of water. Consult a physician. If ingested, give milk, egg white, or large amounts of water.









References:

1. Guft, H. Isolation of Acid fast bacilli from contaminated specimens Health Lab Sc. 8:79, 1971
2. Sommers, H.M. and Good, R.C. Mycobacterium in Manual of Clinical Microbiology, 4th ed. Am.Soc. For Microbiology, Washington, DC 1985.
3. Krasnow, I and Wayne, L.G. Comparison of methods for tuberculosis bacteriology. Appl. Microbiol. 8:915, 1969.
4. Vestal, A.L. Procedures for the isolation and identification of Mycobacteria. U.S.P.H.S. Publ. 75:8230, Center for Disease Control, Atlanta, Ga. 1975.
5. Isenburg, Henry D. Clinical Microbiology Procedures Handbook. ASM Press 2004

Related Product Information:

Cat # 667: Snap N' Digest -75 mL (10 bottles + buffer packets)
Cat # 668: Snap N' Digest – 150 mL (10 bottles + buffer packets)
Cat #669-100 Sterilized TB Buffer (10 x 100ml bottles)
Cat#041-0120 TB Slides (priced per gross)

SYMBOL LEGEND

	Catalog Number
	In Vitro Diagnostic Medical Device
	Consult Instructions for Use (IFU)
	Temperature Limitations (Storage Temp.)
	Batch Code (Lot Number)
	Use By (Expiration Date)
	Quantity Included
	Dimensions

Supported Products Page **(QUALITY FILE ONLY)**

This Technical Insert is used for the following products:

SDL Prod ID	Description			
389	667	.	Snap n' Digest 75ml	10 bottles/pkg
390	668	.	Snap n' Digest 150ml	10 bottles/pkg

Revision History

CR NUMBER	REVISION
0909-001	00
1017-003	01
0420-001	02