SALUBRIS, Inc.

GATEWAY TO HEALTH, WORLDWIDE

DECOMICS®

RAPID DECONTAMINATION AND CONCENTRATION KIT FOR MYCOBACTERIAL CULTURE, MICROSCOPY AND MOLECULAR METHODS

Catalogue #: DEC010 **Instructions for Use** **For In Vitro Diagnostic Use**

Product's name:

DECOMICS®

Product's intended use:

DECOMICS® is a sample decontamination and concentration kit. By eliminating the need for centrifugation, it enables the rapid processing of samples for microscopy, culture and molecular methods, for isolation and identification of mycobacteria[1,2]. It is intended for **in vitro diagnostic use**.

General information:

DECOMICS® is a kit that enables the application of a new safe and easy method of decontamination and concentration. It increases the recovery of mycobacteria by homogenizing samples like sputum and selectively killing other microorganisms that contaminate mycobacterial culture media. ***DECOMICS®*** provides, in individual sets, all the materials needed for processing each sample. Thus, it is ready to use, user-friendly, and it eliminates the problem of cross-contamination. ***DECOMICS®*** saves time and effort by eliminating the need for centrifugation. In all other decontamination and concentration methods[3,4] sample processing requires approximately 45 minutes which is decreased to only approximately 23 minutes by ***DECOMICS®***. Since centrifugation and discarding the supernatant is not required, sample processing becomes safer for the user and for the environment[1,2].

Principles of the procedure:

Clinical samples like sputum contain many microorganisms other than mycobacteria. Processing with high pH solution decontaminates the samples by killing many microorganisms susceptible to sodium hydroxide while mycobacteria, that are resistant to alkaline pH, survive. Neutralizing solution neutralizes the pH. In classical decontamination methods when decontamination and neutralization solutions are added, the specimen is diluted and sedimentation of cells by centrifugation is required for concentration. ***DECOMICS®*** concentrates the sample by removing most of the fluid by absorbent beads. Beads also enable efficient homogenization of the specimen during mixing by vortex[1,2].

Ingredients:

- Specially formulated decontamination solution containing NaOH and a pH indicator.
- Neutralization solution containing a specially formulated buffer solution.

Cautions and warnings:

FOR IN VITRO DIAGNOSTIC USE.

Laboratory procedures involving mycobacteria require special equipment and techniques to minimize biohazards. Specimen preparation must be done in a biological safety cabinet.

DECOMICS® has been designed to minimize risks associated with mycobacterial testing. However, to further reduce the risks of accidental exposure to infectious agents, additional precautions should be taken. At a minimum, specimen manipulation should be done in a contained environment with controlled access, which has a tuberculosis exposure control plan. The locations should have surfaces which can be easily decontaminated using an appropriate topical disinfectant. Pathogenic microorganisms including Hepatitis B Virus and Human Immunodeficiency Virus (HIV) may be present in specimens. Universal precautions and local laboratory guidelines should be followed in handling all items contaminated with blood or other body fluids. If a container is found to be leaking or is accidentally broken during collection or transport, use the established procedures in your facility for dealing with mycobacterial spills. At a minimum, universal precautions should be employed.

General safety precautions:

- Always wear masks and gloves when working with potential biohazard material.
- Work in a laminary flow cabin, biosafety level II, when transferring, homogenizing and pipetting the samples.
- Never use mouth pipetting.
- If spills of the contaminated material occur, disinfect with 2.5% hypochlorite solution.
- If solutions contact skin, eyes or mucosal surfaces, wash immediately and thoroughly with water and seek immediate medical help.
- At a minimum, universal precautions should be employed.
- Tubes should be discarded in an appropriate manner.

Storage instructions:

Store at room temperature, in a dry place

List of materials provided:

List of materials for processing one sample:

- 10 mL of decontamination solution in 50 mL polypropylene sample cup.
- 4.5 mL of neutralization solution in polypropylene tube.
- Absorbent beads in plastic bag.

Each cardboard box contains 40 sets of the materials listed above.

List of materials that are not provided:

Vortex, automatic pipettors, sterile pipette tips, conical centrifuge tube.

Indications of instability or deterioration:

DECOMICS® should not be used if above indicated volumes are not present in each container or if there is turbidity or sediments in the solutions.

Instructions for use:

Sputum and body fluids other than urine:

1- Samples like sputum, broncho alveolar fluid, gastric lavage fluid, pleural, pericardial, or peritoneal fluids may be processed. **For microscopy:** before starting the

decontamination and concentration process, make a direct smear of the sample on a slide and let it dry. This dry smear improves adhesion of the concentrated specimen to the slide and increases the sensitivity of microscopic examination.

2- Transfer a maximum volume of 5 mL of the sample from the collection cup to the sample cup.
3- For any volume up to 5 mL of samples, **empty all** of the red decontamination solution into the sample cup and close the cap securely.
4- Homogenize the sample by vortexing or shaking manually.
5- Leave at room temperature for 15 minutes.
6- First **empty all** the transparent neutralizing solution into the cup in one movement. After emptying the whole neutralization tube, pour **all the beads** contained in the bag into the cup. Close the cap immediately to prevent beads jumping out of the cup.
7- Mix the sample by vortexing or shaking manually.
8- Leave at room temperature for at least 5 minutes. The beads will absorb most of the fluid, concentrating the sample. Some beads may crack and jump in the cup. Do not open the cap until cracking sounds stop.
9- The color of the fluid will first turn from pink to yellow, and then to an orange to pinkish color indicating the pH is adjusted properly.
10- Incline the cup to one side and hit this side of the cup gently to the surface, to collect the beads on one side. Then incline the cup to the opposite side. The concentrated fluid specimen will collect on that side.
11- Take the concentrated sample by a sterile pipette or pipette tip (using an automatic pipettor). This sample can now be used for microscopy, culture, and molecular diagnostic methods. For microscopic examination, put a drop of the specimen on the previously prepared direct smear.

Urine samples:

It is recommended to obtain early morning urine to increase the chance for recovery of mycobacteria. 5 mL of urine sample can directly be used for isolating mycobacteria as described above. However the recovery chance can be increased by centrifugation as follows:

1- Transfer the urine sample from the collection cup into a 50 mL conical centrifuge tube. The tube can be filled up to the 50 mL line. Close the cap tightly.
2- Spin the tube in a centrifuge for 15 minutes at 2000 x g. Using a refrigerated centrifuge with airtight buckets will minimize killing mycobacteria due to heat formation.
3- Discard the supernatant according to the safety rules of your laboratory, leaving approximately 3 mL of concentrated sample.
4- Continue processing the urine sample, according to the instructions for *Sputum and body fluids other than urine*, starting from step 2.

Quality control:

Positive control: Respiratory secretions spiked with mycobacteria.
Negative control: Respiratory secretions spiked with *Escherichia coli* and *Staphylococcus aureus*.

Description of the amounts of reagents necessary, and the parameters of time and temperature:

The only reagents required are those included in the kit. The whole procedure takes approximately 23 minutes. The procedure is performed at room temperature**.**

Time restrictions:

Recommended decontamination time is 15 minutes. Shorter decontamination time may increase the contamination rate. Extension of decontamination time may decrease the number of living mycobacteria.

Limitations of the procedure:

Some organisms other than mycobacteria may survive the decontamination process. If recurrent contamination occurs from a certain specimen, increase decontamination time appropriately.

Bibliography:

1-Kocagoz T., et al. A new decontamination and concentration method which does not require centrifugation. 2012. 1st Clinical Microbiology Congress, Antalya, Turkey. Poster award. Nov. 12-16.
2-Kocagoz T., et al. Revolutionizing decontamination and concentration method for the diagnosis of tuberculosis. 2012. American Society for Microbiology General Meeting, San Francisco, June 16-19.
3-Kubica GP, Dye WE, Cohn ML, Middlebrook G. Sputum digestion and decontamination with N-acetyl-L-cysteine-sodium hydroxide for culture of mycobacteria. 1963. Am. Rev. Respir. Dis. 87:775-779.
4-N-acetyl-L-cysteine-sodium hydroxide method for liquefaction and decontamination of specimens. Bailey & Scott's Diagnostic Microbiology, Ninth Edition. Mosby-Year Book Inc. St. Louis, MO. USA. 1994, p:600.

Manufacturer:

SALUBRIS, Inc.
One Boston Place, Suite 2600
Boston, MA 02108, U.S.A.
Phone: (617) 960-9698
Fax: (617) 249-0803

Authorised representative:

SAS DIAGNOTIS
2, Clos de Toussue, 27300
Menneval – FRANCE
Phone: +33 232 44 28 12

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