TIBO
Trends In Innovative Biotechnology Organization

DECOMICS®

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

Cat. #: 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 eliminates the problem of cross-contamination while saving time and effort. Thanks to the elimination of the need for centrifugation, it saves time and effort. In all other decontamination and concentration methods[3,4] sample processing requires approximately 45 minutes which is decreased to only approximately 20 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].

Limitations of the method:

Some organisms in samples other than mycobacteria, may survive the decontamination procedure.

DECOMICS® is intended as a general-purpose device. No claim or representation is intended for its use to identify any specific organism or for clinical use (diagnostic, prognostic, therapeutic). ***DECOMICS®*** may be used in clinical diagnostic laboratory systems after the laboratory has validated their complete system as required by CLIA '88 regulations in the U.S. or equivalents in other countries.

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 high pH while mycobacteria, that are resistant to alkaline pH, survive. Neutralizing solution neutralizes the pH. The pH indicator, used in ***DECOMICS®*** is red in alkaline pH, yellow in acid pH and pink to orange at neutral pH, and allows monitoring pH during the process. 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. During absorption, bacteria are concentrated in the fluid outside the beads since the pores of the beads are much smaller than bacteria and bacteria cannot penetrate into the beads. Beads also enable efficient homogenization of the specimen during mixing by vortex[1,2].

Ingredients:
One box of ***DECOMICS®*** contains sufficient material for processing 40 samples. The following material is included for each sample:
Sample cup: Contains 10 mL of decontamination fluid
Absorbent beads: In plastic bags
Neutralization solution: 4.5 mL in plastic tube.

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.
- 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.
- Tubes should be discarded in an appropriate manner.

Storage instructions:
Store at room temperature, in a dry place.

DECOMICS®

List of materials provided:

List of materials for processing one sample:

- Polypropylene sample cup containing 10mL of decontamination solution with pH indicator.
- Absorbent beads in plastic bag.
- 4.5 mL neutralizing solution in plastic tube.

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

Indications of instability or deterioration:

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

Instructions for use[2]:

Sputum and body fluids other than urine:

1- Before starting processing the sample make a direct smear on a slide and let it dry (addition of processed sample at the end will help this concentrated specimen stick better to the slide and will increase the sensitivity of microscopic examination).
2- Transfer a maximum volume of 5 mL of samples like sputum, bronchoalveolar fluid, gastric lavage fluid, pleural, pericardial, or peritoneal fluids from the collection cup into the cup containing decontamination fluid.
3- Close the cap securely and homogenize the specimen by vortex or shaking manually.
4- Wait for 10 minutes. (In laboratories with high contamination rates, this decontamination time may be extended up to 15 minutes.)
5- Open the bag of absorbent beads and pour all the beads into the cup. Close the cap immediately to prevent jumping of the beads from the cup. Mix by vortex or by shaking the cup with one hand while hitting the cup into the palm of the other hand.
6- Wait for 5 minutes. During this time period all the decontamination solution, will be absorbed by the beads. Some of the beads may crack and jump in the cup by rapid absorption of the fluid. Do not open the cap until cracking sounds subside.
7- Open the cap and transfer all the neutralizing solution into the cup. Close the cap securely.
8- Mix by vortex or by shaking the cup with one hand while hitting the cup into the palm of the other hand.
9- Wait for 3 minutes (during this period of time most of the fluid will be absorbed by the beads and the sample will be concentrated. The color of the fluid will first turn from yellow and then to pink orange indicating the pH is neutralized).
10- Incline the cup to one side and hit gently this side of the cup 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 concentrated specimen by the help of a sterile pipette or pipette tip (using an automatic pipettor) and inoculate culture media. Put a drop of the specimen on previously prepared direct smear for microscopic examination (the processed specimen can also be used for molecular diagnostic tests).

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 samples from the collection cup into a 50 mL conical centrifuge tube. The tube can be filled up to the 50 mL line.
2- Spin the tubes in a centrifuge for 15 minutes at 3000 x g.
3- Discard the supernatant according to the safety rules of your laboratory. Leave approximately 3 mL of concentrated sample.
4- Continue processing, as described above for other types of samples.

List of materials that are not provided:

Vortex, automatic pipettors, sterile pipette tips.

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 20 minutes. The procedure is performed at room temperature.

Time restrictions:

Decontamination time must be from 10 to 15 minutes. Extension of decontamination time may decrease the number of living mycobacteria.

Limitations of the procedure:

Decontamination may not eliminate completely microorganisms other than mycobacteria. If recurrent contamination occurs from a certain specimen, increasing decontamination time may enable decontamination.

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:

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Catalogue number:

DEC010

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