DECOMICS

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

Catalog No: DEC010-011 | Instructions for Use | For In Vitro Use Only

Product Name:
DECOMICS

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 new method and a kit that eliminates the need for centrifugation and enables easy and safe decontamination and concentration of samples. 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 general and cross-contamination. Eliminating the need for centrifuges provides great savings in terms of time and labor. In all other decontamination and concentration methods 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.

Limitations of the method:
DECOMICS is an important aid in the detection of mycobacteria, but it is not a tool used for mycobacteria diagnosis alone. Some organisms in samples other than mycobacteria, may survive the decontamination procedure.

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. The pH indicator in solutions is red in alkaline pH, yellow in acid pH and pink-orange in neutral pH. A pink-orange color in the processed sample indicates that the pH has been adjusted appropriately. In classical methods, when solutions used in sample processing are added, the sample is significantly diluted. To increase sensitivity, cells should be concentrated by centrifugation. ***DECOMICS*** concentrates the sample by removing most of the fluid by absorbent beads and eliminates the need for centrifugation. Since the pores of the adsorbent beads are much smaller than bacteria, mycobacteria cannot enter the beads during the absorption process and are concentrated in the surrounding liquid. Beads also enable efficient homogenization of the specimen during mixing by vortex.

Ingredients:
DEC010
Enough material for a total of 40 samples.
For each sample:
Sample Cup: 10 mL decontamination solution
Absorbent Beads: Absorbent beads in a bag
Neutralization Solution: 4.5 mL neutralization solution
DEC011
Enough material for a total of 30 samples.
For each sample:
Sample Cup: Sample processing cup
Decontamination Solution: 10 mL decontamination solution
Absorbent Beads: Absorbent beads in a bag
Neutralization Solution: 4.5 mL neutralization solution

Cautions and warnings:
- FOR IN VITRO DIAGNOSTIC USE.
- Laboratory procedures involving mycobacteria require special equipment and techniques to minimize biohazards. Specimen preparation should be performed in a level II biosafety cabinet. People who apply these techniques are recommended to have special training in this area.
- To reduce the risks of accidental exposure to infectious agents, additional precautions should be taken. At a minimum, specimen manipulations should be done in a contained environment having controlled access, which has a tuberculosis exposure control plan. The locations should have surfaces that 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.

General safety precautions:
- Always wear masks and gloves when working with potential biohazard material.
- Work in a laminar flow cabin, biosafety level II, when transferring, homogenizing and pipetting samples.
- Never use mouth pipetting.
- If spills of the contaminated material occur, disinfect with 2.5% hypochlorite solution.
- If the decontamination or neutralization solution comes into contact with the eyes, skin or mucosal surfaces, rinse immediately with water and seek emergency medical attention.
- No part of the kit should be given to children.
- Tubes should be discarded in an appropriate manner according to biosafety principles.

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

Indications of instability or deterioration:
DECOMICS kits should not be used if the above indicated volumes are not present in each container or if there is turbidity or sediments in the solutions.

Application*:*
<u>Sputum and other liquid respiratory samples:</u>

1. For microscopic examination, before starting the sample processing, a smear is made on a slide from the sample and dried (The addition of the processed sample after decontamination and concentration will help the concentrated specimen to stick better to the slide and will increase the sensitivity of microscopic examination and facilitates finding the area and examination under the microscope).
2. Transfer a maximum volume of 5 mL of samples such as sputum, broncho-alveolar washing fluid, gastric fluid, pleural, pericardial or peritoneal fluids in the sample processing cup.
3. Pour 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. Wait for 15 minutes.
6. Pour all the neutralization solution and the absorbent beads into the sample cup. Close the lid of the sample container immediately to prevent the beads from splashing out that may crack during rapid fluid absorption. Shake by hand or with the help of a vortex.
7. Wait for 9 minutes. Do not open the cap until cracking sounds stop.
8. The beads will absorb most of the fluid, concentrating the sample. 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.
9. Tilt the sample cup sideways so that the beads in the container are collected to one side. Then, tilt the sample container slightly in the opposite direction so that the liquid accumulates to the other side. Take the concentrated sample with a pipette and inoculate into the culture tubes. Sample can be placed on the direct smear prepared from unprocessed sputum sample and can be examined under the microscope after staining. Additionally, it can be used for other diagnostic methods like PCR.

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Urine samples:
It is recommended to obtain early morning urine to increase the chance for recovery of mycobacteria.

1. Transfer the urine sample into a 50 mL centrifuge tube up to the 50 mL line.
2. Spin the tube in a centrifuge for 15 minutes at 2000 x g.
3. Discard the supernatant according to the safety rules of your laboratory, leaving approximately 1-3 mL of concentrated sample.
4. Continue processing the urine sample, according to the instructions for other samples, starting from step 2.

List of materials that are not provided:

- Automatic pipettes or pasteur pipettes
- sterile pipette tips
- Specific materials (biosafety cabinet, special filter mask, gloves, etc.) and application guidelines required for the study of mycobacteria and used to minimize biological hazards.

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

Necessary reagents, time and temperature parameters required for application:
The only reagents required are those included in the kit. The whole procedure takes approximately 23 minutes.

Time restrictions:
Decontamination time should be at least 15 minutes. Shorter decontamination times may increase the contamination rate. Extension of decontamination time may decrease the number of living mycobacteria.

Limitations of the procedure:
During the application, after pouring the absorbent beads into the sample container, it is necessary to wait for 5 minutes. If the lid is opened before this time, the absorbent beads may splash out and cause contamination.

Shelf life:
One year.

Bibliography:

1. T. Kocagöz et al. , ***DECOMICS***, A New Decontamination and Concentration Method that does not require centrifugation. First National Clinical Microbiology Congress Antalya, November 12-16, 2011. (Poster award, first prize.)
2. T. Kocagöz 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.

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