

Insert for Urine Kit 98009

REVISION: DBV0039A
DATE OF ISSUE: 04/04/2013
LANGUAGE: English

FOR IN VITRO DIAGNOSTIC USE ONLY

- PRODUCT GROUP:** Kits for susceptibility testing of bacteria obtained from urine samples.
- MANUFACTURER:** ROSCO Diagnostica A/S, Taastrupgaardsvej 30, DK-2630 Taastrup, Denmark.
- INTENDED USE:** Tablets are used for *in vitro* susceptibility testing of bacteria obtained from urine by the agar tablet/disc diffusion method, in order to confirm the choice of appropriate antibiotic treatment.
- INTENDED USERS:** Only to be used by professionals and people trained to work with microbes and disc diffusion testing.
- PRINCIPLE OF THE TEST:** Included in the kit are six cartridges containing common antibiotic substances (NEO-SENSITABS) used in the treatment of urinary tract infection (UTI) and one cartridge (DIATABS), used for the identification of *E. coli* bacteria. The latter is included because approximately 80 % of all urinary tract infections are caused by the *E. coli* variants. Application of this kit in the clinic for the routine screening of UTI's ensures appropriate choice of antibiotic, thereby minimizing the risk of development of resistance mechanisms in bacteria.
- DETAILED INSTRUCTIONS:** ROSCO's detailed Instruction for Use of NEO-SENSITABS and DIATABS should be available in each laboratory working with ROSCO's *Diagnostic products*. The latest edition of Instruction for Use can be seen in and/or printed out from ROSCO's website www.rosco.dk. Here more detailed information can also be found in ROSCO's User's Guide for NEO-SENSITABS and DIATABS in English. Instructions for Use and User's Guide can be obtained free of charge from your local distributor on request, or from ROSCO Diagnostica A/S:
E-mail: info@rosco.dk or
Fax: +45 43 52 73 74

CONTENT AND FORMULATION:

Seven cartridges of tablets, formulated for maximum stability, each containing approximately 50 tablets equivalent to 50 tests:

1. Ampicillin 10 µg, coded AMP10
2. Ciprofloxacin 5 µg, coded CIRP5
3. Mecilinam 10 µg, coded MEC10
4. Nitrofurantoin 100 µg, coded NI100
5. Sulphonamides 240 µg, coded SULFA
6. Trimethoprim 5 µg, coded TRIM5
7. Betaglucoronidase, 6 mm tablet

STORAGE/HANDLING: Store at room temperature until expiry date shown on product label. Opened cartridges (stored in dispenser) must be used within 12 months. Dispensers with open cartridges must never be placed in the refrigerator.

PRECAUTIONS:

For *in vitro* diagnostic use only.

MATERIALS REQUIRED BUT NOT PROVIDED:

Standard microbial equipment such as loops, culture media, incubator etc. and biochemical reagents.

PROCEDURE:

1. Inoculate a Mueller-Hinton agar plate using a fresh urine sample.
2. The urine sample is spread uniformly over the entire surface of the plate. Remove excess.
3. Using a single tablet dispenser, place one of each tablet on the inoculated agar plate, ensuring sufficient space between individual tablets to allow for proper measurement of inhibition zones.
4. Incubate at 35±1°C for 18±2 hours (overnight).
5. Measure and record the diameter of the inhibition zones. No zone around a tablet corresponds to a 9 mm inhibition zone.

INTERPRETATION OF RESULTS:

The results are interpreted by measurement of the inhibition zones of each of the tablets provided in the kit, see table 1 below.

Interpretation of DIATABS Betaglucoronidase tablet:

A positive reaction is seen as yellowish colonies on or around the tablet. Indicating presence of *E. coli* bacteria.

DISPOSAL:

NEO-SENSITABS and agar plates with potential pathogens are disposed of as microbiological waste.

Table 1:

NEO-SENSITABS	Content in µg	Zone of inhibition (mm), confluent growth	
		Susceptible	Resistant
Ampicillin	10	≥ 17 mm	< 14 mm
Ciprofloxacin	5	≥ 22 mm	< 19 mm
Mecillinam	10	≥ 15 mm	< 15 mm
Nitrofurantoin	100	≥ 15 mm	< 15 mm
Sulfonamider	240	≥ 17 mm	< 13 mm
Trimethoprim	5	≥ 18 mm	< 15 mm

REFERENCES:

www.rosco.dk