
Insert for Kit for Detection of COLISTIN resistance in *Enterobacteriaceae*, *P.aeruginosa* and *Acinetobacter* (98018)

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Kit for Detection of COLISTIN resistance in *Enterobacteriaceae*, *P. aeruginosa* and *Acinetobacter*

FOR IN VITRO DIAGNOSTIC USE ONLY

PRODUCT GROUP: Kits for detection of resistance mechanisms

MANUFACTURER: Rosco Diagnostica ApS, Stensmosevej 24A, DK-2620 Albertslund, Denmark.

INTENDED USE: Tablets are used for qualitative *in vitro* identification of microbial resistance mechanisms by the agar tablet/disc diffusion method, in order to confirm the mechanism by which the organism has gained resistance to specific antimicrobial agents.

INTENDED USERS: Only to be used by professionals and people trained to work with microbes and disc diffusion testing.

PRINCIPLE OF THE TEST:
Prediffusion method: The principle of the prediffusion method was developed by the Danish microbiologist Frølund-Thomsen. The idea is to give high molecular weight antimicrobials, a longer period of time to diffuse into the agar, before bacterial growth takes place. The prediffusion technique results in a much larger zone size difference between consecutive MIC values, approx. 5 mm with the prediffusion method compared to 1 to 1.5 mm with normal diffusion method. This results in a much more secure differentiation between susceptible isolates and isolates with reduced susceptibility or resistance.

DETAILED INSTRUCTIONS: Rosco Diagnostica's detailed Instruction for Use for Detection of resistance mechanisms should be available in laboratories working with Rosco Diagnostica's Diagnostic products.

Latest version of Instruction for Use can be seen in and/or printed out from Rosco Diagnostica's website www.rosco-diagnostica.com
Users Guide can be obtained free of charge from your local distributor on request, or from Rosco Diagnostica:

E-mail: info@rosco-diagnostica.com

Phone: +45 93 40 65 65

CONTENT AND FORMULATION:

2 cartridges of COLISTIN Prediffusion Neo-Sensitabs, formulated for maximum stability, each containing 50 tablets. Totaling 100 tests

STORAGE/HANDLING:

Store at room temperature until expiry date printed on product label.

PRECAUTIONS:

For *in vitro* diagnostic use only. Safety precautions should be taken and aseptic techniques used when working with potential biohazards. To be used only by adequately trained and qualified laboratory personnel. Sterilize all biohazard waste before disposal. Refer to Product Safety Data Sheet.

MATERIALS REQUIRED BUT NOT PROVIDED:

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

PROCEDURE:

One COLISTIN Prediffusion Neo-Sensitabs is placed on an uninoculated Mueller Hinton agar plate.

After 2 hours in the incubator at 35-37°C, the tablet (disc) is removed (by knocking the plate against the table). Maintain the plate at room temperature for further 18 – 22 hours. The plate is now inoculated with the strain to be tested, using a McFarland 0.5 inoculum. The plate is incubated overnight at 35 degrees Celsius. Measure and record the diameter of the inhibition zones. Compare with the corresponding zone breakpoints.

Please note: The prediffusion plate can be prepared the day before it is inoculated, to avoid loss of time and results will be available within 24 hours. Surplus of prediffused plates may be kept in the refrigerator for another 24 hours.

INTERPRETATION OF RESULTS:

The results are interpreted by comparing the inhibition zones with the following standards:

Enterobacteriaceae and Ps. aeruginosa

S >= 16 mm; I: 15 – 12 mm and R < 12 mm,
corresponding to MICs S <= 2 µg/ml and R > 4 µg/ml

Acinetobacter spp

S > = 20 mm and I: 19 – 14 mm and R < 14 mm,

corresponding to MICs S \geq 2 μ g/ml and R > 4 μ g/ml

Use table 1 to assist in the interpretation

QUALITY CONTROL:

Although Rosco Diagnostica ApS produces the most stable diffusion discs (tablets) it is necessary to perform regular quality control. .

As Q. C. strains the following may be used:

E. coli ATCC 25922

Ps. aeruginosa ATCC 27853.

Table 1: COLISTIN Prediffusion Sensitive Intermediate

Resistant

Enterobacteriaceae	\geq 16 mm	15-12 mm	< 12 mm
Ps aeruginosa	\geq 16 mm	15-12 mm	< 12 mm
Acinetobacter spp.	\geq 20 mm	19-14 mm	< 14 mm

REFERENCES:

Please see the Colistin Regression line on the website, Doc. Area EUCAST Regression Lines

1. Boyen F et al: Disk prediffusion is a reliable method for testing Colistin susceptibility in porcine E. coli strains. *Vet Microbiol* **144**,359-362, 2010.
2. Nastro M et al: Evaluation of the prediffusion method for Colistin in Klebsiella pneumoniae. *Rev Argent Microbiol* **44**, suppl 1, P40, 2012.
3. Herrera ME et al: Comparative evaluation of the sensitivity of Acinetobacter to colistin, using the prediffusion and MIC methods. *Detection of heteroresistant isolates. Rev Argent Microbiol* **43**, 115-119, 2011.

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