Insert for Kit for Detection of hGISA, GISA, VRE and Daptomycin susceptibility 98017

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Kit for Detection of hGISA, GISA, VRE and Daptomycin susceptibility

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 the 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 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 from Rosco Diagnostica's website www.rosco-diagnostica.com

User's 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: 3 cartridges of tablets, formulated for maximum stability, each containing approximately 50 tablets:

1. Vancomycin 30 µg, coded VAN30
2. Teicoplanin 30 µg, coded TEI30
3. Daptomycin 30 µg, coded DAP30

STORAGE/HANDLING:

Store at room temperature until expiry date shown on the product label. Cartridges may be opened and closed several times without affecting the shelflife of the products

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:

1. One Neo-Sensitabs of each Vancomycin 30 µg, Teicoplanin 30 µg and Daptomycin 30 µg are placed on an uninoculated Mueller Hinton agar plate.
2. After 2 hours in the incubator at 35-37 °C, the tablet (disc) is removed (by knocking the plate against the table), but prior to this a short name (VAN, TEI, DAP) is written on the back of the plate in order to identify the different antimicrobials.
3. Place the plate at room temperature for further 18 – 22 hours.
4. 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.

5. Measure and record the diameter of the inhibition zones. No zone around a tablet corresponds to a 9 mm inhibition zone. 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 of the different tablets with the following standards:

Staphylococci

1. Teicoplanin zone < 20 mm **or** Vancomycin zone < 20 mm. The isolate is a hGISA or hVISA.
2. Teicoplanin zone < 20 mm **and** Vancomycin zone < 20 mm. The isolate is a GISA.
3. Daptomycin zone >= 22 mm (susceptible, MIC <= 1 µg/ml)). Zone < 20 mm (non-susceptible, MIC >= 2 µg/ml)

Enterococci

1. Vancomycin no zone and Teicoplanin no zone : Van A
2. Vancomycin zone < 16 mm (hazy) and Teicoplanin zone > 20 mm : Van B
3. Vancomycin zone < 12 mm (sharp edge) and Teicoplanin zone >20 mm : Van C
4. Daptomycin zone >= 12 mm (MIC <= 4 µg/ml): susceptible. No zone: resistant.

Use table 1 to assist in the interpretation

QUALITY CONTROL:

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

As Q. C. strains the following may be used:
Staph aureus ATCC 700698; hVISA and Daptomycin susceptible
Staph aureus AST 403, GISA and Daptomycin susceptible
Enterococcus faecalis ATCC 51299, Van B.
Staph aureus AST 408, GISA and Daptomycin resistant.

Table 1:

		Vancomycin 30 ug	Teicoplanin 30 ug	Daptomycin 30 ug
hGISA		< 20 mm or	< 20 mm	
GISA		< 20 mm and	< 20 mm	< 5mm
VRE	Van A Van B Van C	no Zone 16mm(hazy) < 12 mm (sharp)	No zone > 20 mm > 20 mm	
Daptomycin resistance	**Staphylococci**			< 20 mm
	Enterococci			no zone
	Streptococci			>= 26 mm (S) < 22 mm (R)

REFERENCES:

1 Nielsen SV, Casals JB : Detection of decreased susceptibility to glycopeptides in S. aureus using tablet(disc) prediffusion.15th ECCMID, april 2005.

2 Koeth L et al: Multisite evaluation of the Daptomycin Neo-Sensitabs prediffusion method against 20 S. aureus. ECCMID p-1065, Milano 2011.

3 Silveira A CO et al: Is prediffusion test an alternative to improve accuracy in screening hVISA strains and to detect susceptibility to glycopeptides/lipopeptides? Diagn Microbiol Infect Dis, accepted manuscript 2014.