



Ecopathology Uro Kit- I, Modified

K084B

Intended Use:

Recommended for isolation and differentiation of Urinary pathogens on the basis of Lactose fermentation subsequent antibiotic susceptibility testing.

Kit Contents**

Product	Code	Packing
a. CLED Agar W/ Bromothymol Blue	SM792	1x100 ml
b. Mueller Hinton Agar	SM173	2x100 ml
c. Sterile Petri plates (Empty 90mm)		15 nos.
d. Octodiscs	OD066R	5 nos.
	OD067R	5 nos.
e. Sterile uricol		5 nos.

Directions

1. Collect the midstream urine sample in sterile uricol. 2. Process the samples as per the protocol. 3. SM792 and SM173 - Slightly loosen the cap and melt the medium in water bath at 100°C. Cool to 45-50°C and pour the medium into empty sterile 90 mm Petri plates. 4. Isolate the organisms from the urine sample on SM792 (CLED Agar w/ BTB). Incubate at 35-37°C for 18-24 hours. 5. The most predominant organism (causative agent) is then selected for sensitivity study. 6. 0.1 OD colony suspension of the suspected organism is prepared and then swabbed on SM173 (Mueller Hinton Agar plates). 7. Place OD066R and OD067R on the swabbed plates. Incubate at 35-37°C for 18-24 hours. 8. Interpret the results after incubation.

Principle And Interpretation

Ecopathology Uro Kit- I, Modified kit is very economical and rapid diagnostic kit for use. Thus the urinary tract infections are bacterial infections affecting parts of urinary tract. The common symptoms of urinary tract infection are urgency and frequency of micturition, with associated discomfort or pain. The common condition is cystitis, due to infection of the bladder with a uropathogenic bacterium, which most frequently is *Escherichia coli*, but sometimes *Staphylococcus saprophyticus* or especially in hospital-acquired infections, *Klebsiella* species, *Proteus mirabilis*, other coliforms, *Pseudomonas aeruginosa* or *Enterococcus faecalis* (1).

Type of specimen

Clinical samples - urine

Specimen Collection and Handling:

Inoculate the medium immediately after urine collection (2,5). After isolation of the organism sensitivity of the organism to antimicrobial agents is checked on Mueller Hinton Agar by disc diffusion method as described in CLSI Approved Standard (6). The susceptibility is determined by comparing with CLSI standards (7). For Susceptibility testing Octodiscs (OD066R & OD067R) are used. These series of discs gives the privilege to study large number of antibiotics at one time. The symbols and concentrations of antimicrobials present are indicated in respect of each peripherally located disc. After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions :

In Vitro diagnostic Use only. Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets

Limitations :

1. Initiation of antibiotic therapy, before collection of sample, low urine pH (less than 5) etc. may result in low bacterial count from infected patients.
2. This medium is recommended for susceptibility testing of pure cultures only.
3. Inoculum density may effect the zone size. Heavy inoculum may result in smaller zones or too less inoculum may result in bigger zones.

4. As antimicrobial susceptibility is carried with antibiotic disc, proper storage of the disc is desired which may effect the potency of the disc.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance

SM792: Sterile glass bottle containing slightly opalescent CLED Agar w/BTB).

SM173: Sterile glass bottle containing slightly opalescent Mueller Hinton Agar.

OD066R/OD067R: Flat circular ring of inert material w/ 8 equidistant arms on the outer periphery, each arm having a 6 mm disc at the end; each disc impregnated w/ different antibiotics, w/ corresponding symbols & concentrations printed on the ring.

Each ring of OD066R contains

Antibiotic	Concentration
Cefoperazone (CPZ)	75µg
Cefpodoxime (CPD)	10µg
Ceftazidime (CAZ)	30µg
Cefepime (CPM)	30µg
Meropenem (MRP)	10µg
Gentamicin (GEN)	10µg
Amikacin (AK)	30µg
Moxifloxacin (MO)	5µg

Each ring of OD067R contains

Antibiotic	Concentration
Ampicillin (AMP)	10µg
Cefazolin (CZ)	30µg
Nalidixic acid (NA)	30µg
Norfloxacin (NX)	10µg
Ciprofloxacin (CIP)	5µg
Co-Trimoxazole (COT)	25µg
Levofloxacin (LE)	5µg
Nitrofurantoin (NIT)	300µg

Colour

SM792: Green coloured medium.

SM173: Light amber coloured medium.

pH

SM792 : 7.10-7.50

SM173 : 7.20-7.40

Sterility test

Passes release criteria

Cultural Response

SM792: Cultural characteristics observed after melting the medium and pouring into sterile Petri plates. The plates are inoculated with the specimen and incubated at 35-37°C for 18-24 hours.

Organism	Inoculum (CFU)	Growth	Recovery	Colour of Colony
<i>Enterococcus faecalis</i> ATCC 29212 (00087*)	50-100	good-luxuriant	>=70%	slight yellowish or greenish
<i>Escherichia coli</i> ATCC 25922 (00013*)	50-100	good-luxuriant	>=70%	yellow, opaque, centre slightly deeper yellow
<i>Klebsiella pneumoniae</i> ATCC 13883 (00097*)	50-100	good-luxuriant	>=70%	yellow to whitish blue
<i>Proteus vulgaris</i> ATCC 13315	50-100	good-luxuriant	>=70%	blue
<i>Salmonella</i> Typhi ATCC 6539	50-100	good-luxuriant	>=70%	bluish

Staphylococcus aureus subsp. *aureus* ATCC 25923 (00034*) 50-100 good-luxuriant $\geq 70\%$ deep yellow

SM173 : Cultural characteristics observed after melting the medium and pouring into sterile Petri plates. The plates are inoculated with the isolated test organisms by swabbing and placing the Octodiscs OD066R & OD067R and incubated at 35-37°C for 18-24 hours.

The following average diameter of zone of inhibition is observed for standard cultures as per CLSI.

OD066R

Organisms(ATCC)	Antibiotic	Std.Zone of diameter(mm)
<i>Escherichia coli</i> ATCC 25922 (00013*)	Cefaperazone CPZ (75mcg)	28 -34 mm
	Cefpodoxime CPD (10mcg)	23 -28 mm
	Ceftazidime CAZ (30mcg)	25 -32 mm
	Cefepime CPM (30mcg)	31 -37 mm
	Meropenem MRP (10mcg)	28 -34 mm
	Gentamicin GEN (10mcg)	19 -26 mm
	Amikacin AK (10mcg)	19 -26 mm
<i>Staphylococcus aureus</i> subsp <i>aureus</i> ATCC 25923 (00034*)	Moxifloxacin MO (5mcg)	28 -35 mm
	Cefaperazone CPZ (75mcg)	24 -33 mm
	Cefpodoxime CPD (10mcg)	19 -25 mm
	Ceftazidime CAZ (30mcg)	16 -20 mm
	Cefepime CPM (30mcg)	23 -29 mm
	Meropenem MRP (10mcg)	29 -37 mm
	Gentamicin GEN (10mcg)	19 -27 mm
<i>Pseudomonas aeruginosa</i> ATCC 27853 (00025*)	Amikacin AK (10mcg)	20 -26 mm
	Moxifloxacin MO (5mcg)	28 -35 mm
	Cefaperazone CPZ (75mcg)	23 -29 mm
	Ceftazidime CAZ (30mcg)	22 -29 mm
	Cefepime CPM (30mcg)	24 -30 mm
	Meropenem MRP (10mcg)	27 -33 mm
	Gentamicin GEN (10mcg)	16 -21 mm
Amikacin AK (10mcg)	18 -26 mm	
	Moxifloxacin MO (5mcg)	17 -25 mm

OD067R

Organisms(ATCC)	Antibiotic	Std.Zone of diameter(mm)	
<i>Escherichia coli</i> ATCC 25922 (00013*)	Ampicillin AMP (10mcg)	16 -22 mm	
	Cefazolin CZ (30mcg)	23 -29 mm	
	Nalidixic acid NA (30mcg)	22 -28 mm	
	Norfloxacin NX (10mcg)	28 -35 mm	
	Ciprofloxacin CIP (5mcg)	30 -40 mm	
	Co-Trimoxazole COT (25mcg)	23 -29 mm	
	Levofloxacin LE (5mcg)	29 -37 mm	
	Nitrofurantion NIT (300mcg)	20 -25 mm	
	<i>Staphylococcus aureus</i> subsp <i>aureus</i> ATCC 25923 (00034*)	Ampicillin AMP (10mcg)	27 -35 mm
		Cefazolin CZ (30mcg)	29 -35 mm
Norfloxacin NX (10mcg)		17 -28 mm	
Ciprofloxacin CIP (5mcg)		22 -30 mm	
Co-Trimoxazole COT (25mcg)		24 -32 mm	
<i>Pseudomonas aeruginosa</i> ATCC 27853 (00025*)	Levofloxacin LE (5mcg)	25 -30 mm	
	Norfloxacin NX (10mcg)	22 -29 mm	
	Ciprofloxacin CIP (5mcg)	25 -33 mm	
Levofloxacin LE (5 mcg)	19 -26 mm		

Key : (*) Corresponding WDCM numbers.

Storage and Shelf Life

Store below 2-8°C. Use before expiry date on the label. On opening, product should be properly stored dry and ventilated area protected from extremes of temperature and sources of ignition. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (3,4).

Reference

1. Collee J. G., Fraser A. G., Marmion B. P., Simmons A., (Eds.), Mackie and McCartney, Practical Medical Microbiology, 1996, 14th Edition, Churchill Livingstone.
2. Dixon J. M. S. and Clark M. A., 1968, Conc. Med. Assoc. J., 99 (15)
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6. NCCLS Approved Standard: ASM-2, 1979, Performance Standards for Antimicrobial disc Susceptibility Tests, 2nd Ed., National Committee for Clin. Lab. Standards.
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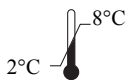
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In vitro diagnostic medical device



CE Marking



Storage temperature



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