Technical Data

Ecopathology Uro Kit -4 K090

Recommended for diagnosis of Urinary Tract Infection and subsequent antibiotic susceptibility testing.

Kit Contents**

a. HiCrome™ UTI Agar (SM1353) : 1x100ml
b. Mueller Hinton Agar (SM173) : 3x100ml
c. Sterile Petri plates : Empty 90 mm - 5Nos (for SM1353) and 120mm - 10 Nos for (SM173)
d. Octodiscs : OD022- 5 Nos, OD021 - 5 Nos, (Each OD is a combination of 8 different antibiotics)
e. Sterile Uricol : 5 Nos

Directions

1. Collect the midstream urine sample in sterile uricol. 2. Process the samples as per the protocol. 3. SM1353 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 HiCrome™ UTI Agar plate prepared from SM1353. 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 Mueller Hinton Agar plates plate prepared from SM173. 7. Place OD021 and OD022 on the swabbed plates. Incubate at 35-37°C for 18-24 hours. 8. Interpret the results after incubation.

Principle And Interpretation

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). HiCrome™ UTI Agar is also recommended for dip stick procedures and as dip inoculum transport medium for urine specimens. Inoculate the medium immediately after urine collection (5, 2). 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 Susceptilbility testing OD021 or OD022 are used. These series of discs gives the privilege to study large number of antibiotics at one time.

Type of specimen

Clinical samples - urine

Specimen Collection and Handling:

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (3,4). 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 guidleines should be followed while handling clincal specimens. Saftey 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

SM1353: Sterile glass bottle conataining slightly opalescent HiCrome™ UTI Agar.
SM173: Sterile glass bottle conataining slightly opalescent Mueller Hinton Agar.
OD021 or OD022: 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 OD021 contains

Antibiotic	Concentration
Clindamycin (Cd)	2µg
Chloramphenicol (C)	30µg
Erythromycin (E)	15µg
Penicillin-G (P)	10units
Tetacycline (TE)	30µg
Carbenicillin (Cb)	100µg
Metronidazole (Mt)	5µg
Cefoxitin (CX)	30µg

Each ring of OD022 contains

Antibiotic	Concentration
Ampicillin (Amp)	10µg
Cefotaxime (CTX)	30µg
Co-Trimoxazole (COT)	25µg
Gentamicin (GEN)	10µg
Nalidixic acid (NA)	30µg
Nitrofurantoin (NIT)	300 µg
Norfloxacin (NX)	10 µg
Cephalothin (CEP)	30µg

Colour

SM1353: Light amber coloured
SM173: Light amber coloured medium.

pH

SM1353: 6.60-7.20
SM173 : 7.20-7.40

Sterility test

Passes release criteria

Cultural Response

SM1353: 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
Enterococcus faecalis ATCC 29212 (00087*)	50-100	good-luxuriant	>=70%	slight yellowish or greenish
Escherichia coli ATCC 25922 (00013*)	50-100	good-luxuriant	>=70%	yellow, opaque, centre slightly deeper yellow
Klebsiella pneumoniae ATCC 13883 (00097*)	50-100	good-luxuriant	>=70%	yellow to whitish blue
Proteus vulgaris ATCC 13315	50-100	good-luxuriant	>=70%	blue
Salmonella Typhi ATCC 6539	50-100	good-luxuriant	>=70%	bluish

Staphylococcus aureus subsp. *aureus* ATCC 25923 (00034*)	50-100	good-luxuriant >=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 OD021/R or OD022/R 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.

OD021

Organisms(ATCC)	Antibiotic	Std.Zone of diameter(mm)
Escherichia coli ATCC 25922 (00013*)	Carbenicillin (CB)	23 -29 mm
	Cefoxitin (CX)	23 -29 mm
	Chloramphenicol (C)	21 -27 mm
	Tetracycline (TE)	18 -25 mm
Staphylococcus aureus subsp *aureus* ATCC 25923 (00034*)	Cefoxitin (CX)	23 -29 mm
	Clindamycin (CD)	24 -30 mm
	Chloramphenicol (C)	19 -26 mm
	Erythromycin (E)	22 -30 mm
	Penicillin-G (P)	26 -37 mm
	Tetracycline (TE)	24 -30 mm
Pseudomonas aeruginosa ATCC 27853 (00025*)	Carbenicillin (CB)	18 -24 mm

Clostridium perfringens ATCC 12924

35 mcg concentration found to be susceptible(Medium of test - Fluid Thioglycollate Medium,Incubation Temperature - 37°C for 24 hours)

OD022

Organisms(ATCC)	Antibiotic	Std.Zone of diameter(mm)
Escherichia coli ATCC 25922 (00013*)	Ampicillin (AMP)	16 -22 mm
	Cephotaxime (CTX)	29 -35 mm
	Cephalothin (CEP)	15 -21 mm
	Co-trimoxazole (COT)	23 -29 mm
	Gentamicin (GEN)	19 -26 mm
	Nalidixic acid (NA)	22 -28 mm
	Nitrofurantoin (NIT)	20 -25 mm
	Norfloxacin (NX)	28 -35 mm
Staphylococcus aureus subsp *aureus* ATCC 25923 (00034*)	Ampicillin (AMP)	27 -35 mm
	Cephotaxime (CTX)	25 -31 mm
	Cephalothin (CEP)	29 -37 mm
	Co-trimoxazole (COT)	24 -32 mm
	Gentamicin (GEN)	19 -27 mm
	Nitrofurantoin (NIT)	18 -22 mm
	Norfloxacin (NX)	17 -28 mm
Pseudomonas aeruginosa ATCC 27853 (00025*)	Cephotaxime (CTX)	18 -22 mm
	Gentamicin (GEN)	16 -21 mm
	Norfloxacin (NX)	22 -29 mm

Key : (*) Corresponding WDCM numbers.

Storage and Shelf Life

Store between 2-8°C.Use before expiry date on the label. On opening, product should be properly stored dry 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).

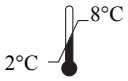
Reference

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. Dixson J. M. S. and Clark M. A., 1968, Conc. Med. Assoc. J., 99 (15)
3. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.
4. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.
5. MacKey and Sandys, 1966, Br. Med. J., 1:1173.
6. NCCLS Approved Standard: ASM-2, 1979, Performance Standards for Antimicrobic disc Susceptibility Tests, 2nd Ed., National Committee for Clin. Lab. Standards.
7. National Committee for Clinical Laboratory Standards, 1986, Proposed Standards, M6-P, NCCLS, Villanova, Pa.

Revision : 00/2021

In vitro diagnostic medical device

CE Marking



Storage temperature

Do not use if package is damaged

HiMedia Laboratories Pvt. Limited,
23 Vadhani Industrial Estate,
LBS Marg,Mumbai-86,MS,India

CE Partner 4U ,Esdoornlaan 13, 3951
DB Maarn The Netherlands,
www.cepartner 4u.eu