28 PIERRE KÖENIG ST., TALPIOT INDUSTRIAL AREA
POB 53231 JERUSALEM 91531 ISRAEL
TEL. **972-2-6781861** FAX. **972-2-6781852**
e-mail: info@novamed.co.il
www.novamed.co.il

THE STANDARDS INSTITUTION OF ISRAEL

Urine Culture DIPSLIDE: C.L.E.D. /MacConkey

the novel method for transport, screening, isolation and identification of bacterial contamination in urine samples
Catalog no. BD-901

INTENDED USE
DipSlide is a convenient device for transporting urine samples as well as for isolating, enumerating and identifying specific bacteria in urine. ***DipSlide*** is intended for use in both physicians' office laboratories and clinical laboratories.

SUMMARY AND EXPLANATION
Novamed's *D*ipslide is a simple, convenient and easy-to-use sampling device for assessing microbial contamination of urine. *D*ipslide can be used to monitor microbial growth wherever the potential may exceed 10^2 microorganisms in ml of urine sample. *D*ipslide***s*** provide a simple, faster, safer and convenient alternative to the traditional plate culturing methods for detection of microbial present. *D*ipslide***s*** unit consists of two different agar modifications attached back-to-back on a plastic sampling paddle, which is permanently fastened to the cap for comfort of handling during use and housed in a closed transparent plastic tube. *D*ipslide***s*** are self-contained units, which can be taken to the sampling site instead of transporting samples, back to the laboratory. *D*ipslide***s*** are available with a variety of growth specific media.

SPECIMEN COLLECTION
Cleanse the genital area and collect a midstream urine specimen in a sterile container. Inoculate the urine as soon as possible after collection.

PROCEDURE
1. Unscrew the protective ***DipSlide*** vial cap and remove the culture paddle.
2. Dip the culture paddle into the sample or pour the sample over agar surfaces, if the volume of sample is not adequate to fully immerse the agar surfaces.
3. Replace inoculated culture paddle in its protective ***DipSlide*** vial and close cap.
4. Transport ***DipSlide*** vial to laboratory for incubation and examination.
5. Place inoculated ***DipSlide*** vial upright in incubator (35°C±2 °C) for 18-24 hours. **Before incubation, loosen cap one-half turn.**
6. Interpret the results by simple visual comparison of bacterial growth on the agar surface with the Colony Density Chart provided. **No actual colony counting is necessary.**

REAGENTS
Following combination of agars is used in manufacturing of ***Dipslide*** **BD-901: C.L.E.D agar and MacConkey agar.**

CLED AGAR's electrolyte deficiency inhibits swarming of Proteus which otherwise would obscure the observation of colonies. Lactose is included in the agar to detect lactose fermenting coliform contaminants which are easily recognized by the green to yellow color change of the agar.

MACCONKEY AGAR is a selective and differential medium for detection of coliform organisms and enteric pathogens. The concentration of bile salts in this medium is relatively low in comparison with other enteric plating medium; therefore selectivity for gram-negative bacteria is not as great as in some other formulations. Crystal violet inhibits gram-positive microorganisms, especially enterococci and staphylococci. Differentiation of enteric micro-organisms is achieved by the combination of lactose and the neutral red indicator. Colorless or pink to red colonies are produced depending upon the ability of the isolate to ferment lactose.

PRECAUTIONS
1. For *in vitro* diagnostic use only.
2. Use aseptic technique and established laboratory procedure in handling and disposing of infectious materials.
3. Dispose of used ***DipSlides*** and tubes by burning, autoclaving or immersing in a suitable disinfectant overnight.

STORAGE
Store either at 2-8°C or 15-25°C until expiry date indicated on the label. Store away from direct sunlight.

READING THE RESULTS

CLED/MacConkey
Remove the paddle from the tube. Observe the bacterial growth on both agars. Count and compare the number of bacteria growing on the CLED to the chart or to the guidelines for enumeration of bacteria. ***DipSlide*** is capable of detecting bacteria in urine at concentrations as low as 100 CFU/ml. The colony density chart allows the reporting of colony counts to the nearest power of 10. If bacterial content is above

10^6 CFU/ml, no single colony can be isolated because of confluent growth. A standard quantitative urine culture should be performed.

Interpretation of Results

In the past, the presence of $\geq 10^5$ CFU/ml was regarded as a positive result while $\leq 10^4$ CFU/ml was negative. From 10^4 to 10^5 CFU/ml were considered borderline cases, which called for repeat examination. Today, the trend is for specific medical departments such as Urology, Nephrology and Pediatrics to report down to 10^3 CFU/ml. Use the attached colony density chart for reporting results. If bacterial growth yields three or more different kinds of colonies, this is most likely due to contamination. The test should be repeated. Preliminary identification of the bacteria can be made based on type and color of colonies.

For example:

Organism	CLED	MacConkey
E. coli	Yellow, darker center	Pink red
K. pneumoniae	Mucoid yellow	Pink red
P. aeruginosa	Matte green-blue	Colorless
P. vulgaris	Clear green-blue	Colorless
S. aureus	Deep yellow	No growth
S. epidermidis	White or pale yellow	No growth
E. faecalis	Yellow	No growth

USER QUALITY CONTROL

Quality control tests are performed on each lot of *DipSlide* at the time of manufacture. Product users who wish to perform their own quality control may use the following procedure.

Prepare a suspension (10^4-10^5 CFU/ml) of each of the following organisms in culture-negative urine from a healthy individual. Confirm the exact organism concentration by inoculating 10 µl with a calibrated loop on reference plates of CLED and MacConkey agar.

Test according to the PROCEDURE.

If the device does not support the expected growth of organisms, it has deteriorated and should not be used.

TYPICAL CULTURAL RESPONSE (after 24 hours at 35°C±2 °C)

ORGANISM	ATCC	CLED Agar	MacConkey Agar
E. coli	**25922**	Yellow colonies, medium becoming yellow	Pink colonies
S. aureus	**25923**	Yellow colonies, yellow medium	Inhibited
P. mirabilis	**12453**	Translucent colonies, medium becoming blue	Translucent, colorless colonies

References

[1] Balows, A. et al. eds. 1991. Manual of clinical microbiology, 5th ed. Amer. Soc. Microbiol., Washington DC.

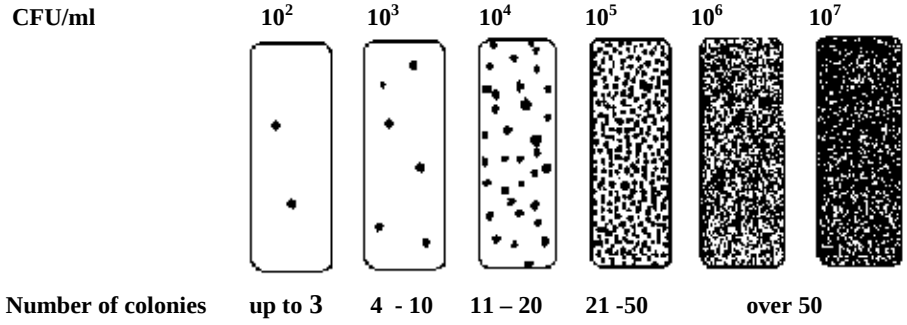
[2] Clarridge, J.E. 1987. Laboratory diagnosis of urinary tract infections. Amer. Soc. Microbiol., Washington DC.

[3] Guttmann, D. 1967. Dip-slide: an aid to quantitative urine culture in general practice. Br. Med. J. 3:343-345.

[4] Blondeau, JM et al. 1995. Evaluation of the Cult Dip Plus dip slide method for urinary tract infection. J. Clin. Pathol. 48:710713.

[5] Difco Laboratories. 1984. Dehydrated culture media and reagents for microbiology, p.546-551. *In* Difco manual, 10th ed.

Colony Density Chart



Manufactured by: 28 PIERRE KOENIG ST., TALPIOT INDUSTRIAL AREA, JERUSALEM 93469, ISRAEL
POB 53231 JERUSALEM 91531 ISRAEL TEL. 972-2-6781883 FAX. 972-2-6781852