LICKSON®

CE

TECHNICAL SHEET

NICKERSON CANDIDA AGAR WITH SWAB

IVD in Class A, EU Reg. 2017/746
For in vitro diagnostic use **IVD**

Screening device consisting of a swab and a test tube containing a selective medium able to change color (from light amber to brown-black) in response to the presence of Candida spp. in clinical samples.

DESCRIPTION

Screening device consisting of a swab and a test tube containing a selective medium able to change color (from light amber to brown-black) in response to the presence of Candida spp. in clinical samples.

PRINCIPLE

The medium contained in the tube – **Biggy Agar (Nickerson)** - is a selective and differential medium used in the detection, isolation and presumptive identification of Candida species. Bismuthyl hydroxy sulphite complex produced into the medium by heat, is extracellularly reduced by Candida spp. to sulphide in a neutral or acidic environment and his reduction, depending on the intensity, results in brown to black pigmentation of the yeast colonies. Bismuth sulphite, bismuth ammonium citrate, glycine at high concentrations, act as selective compounds and the medium is not favourable for the development of schizomycetes; yeast extract and glucose are the nutritive bases.

Biggy Agar (Nickerson):

COMPOSITION	g/L
Glycine	10.0
Bismuth ammonium citrate	5.00
Sodium sulphite	3.00
Glucose	10.0
Yeast Extract	1.00
Agar	13.0

pH finale 6,8 ± 0,2 a 25°C

WARNING AND PRECAUTIONS

For in vitro diagnostic use.
Observe the precautions normally taken when handling laboratory reagents.
Prepared Medium: The product does not contain hazardous substances in concentrations exceeding the limits set by current legislation and therefore is not classified as dangerous.
Safety Data Sheet is available on request for professional users.
Disposal of waste (hazardous waste with infectious risk) must be carried out according to national and local regulations in force.

STORAGE AND STABILITY

NICKERSON CANDIDA AGAR WITH SWAB
10-25°C

NICKERSON CANDIDA AGAR WITH SWAB is stable until the expiration date indicated on the label under the recommended storage conditions.

INSTRUCTIONS FOR USE

- Nickerson Candida Agar with Swab is intended for the bacteriological processing of non-sterile clinical specimens such as mouth, throat, pharyngeal, vaginal swabs.
- Do not deviate from the intended use. Do not use the product if it is expired or the package is opened/damaged. Sterility guaranteed if unopened.
- Use the device following aseptic procedures. Single-use device; do not reuse. Reusing the device could contaminate the sample and/or the patient.
- Keep the device away from heat sources.
- Store in a cool, dry place at a temperature between +10°C and +25°C. Do not freeze.
- After use, the device may contain infectious microorganisms. Use appropriate PPE and dispose of the test tube and swab according to current regulations for Medical waste.

HOW TO USE

1) Remove the swab and tube containing Biggy Agar (Nickerson) from the box.
2) Open the blister pack and aseptically remove the swab from the pack.
3) Collect specimens before antimicrobial therapy where possible. Good laboratory practices for collection of the clinical specimens should be applied.
4) Unscrew the cap and insert the swab into the test tube.
5) Break the swab in the test tube. Discard the broken part of the shaft in accordance with current regulations for medical waste.
6) Firmly tighten the cap onto the test tube and label the test tube with the patient's data.
7) Incubate in aerobic conditions at 30±2°C for 18-72 h and examine daily for evidence of sulphite reduction.
8) The medium changes color (from light amber to brown-black) in response to the presence of Candida spp. This diagnosis must be confirmed at least by microscopic examination and/or other diagnostic tests.

QUALITY CONTROL: Biggy Agar (Nickerson)

Appearance: light amber agar with flocculent precipitate..

In accordance with the predefined Company Quality System, each lot of **NICKERSON CANDIDA AGAR WITH SWAB** is tested against predetermined specifications to ensure consistent product quality.

Typical response after incubation at 30±2°C for 18-48 hours, in aerobiosis:

MICROORGANISM	GROWTH
Candida albicans ATCC 60193	Growth with brown-black colonies
Candida tropicalis NCPF 8841	Growth with dark brown colonies and metallic sheen
E. coli ATCC 25922	Growth inhibited
S. aureus ATCC 25923	Growth inhibited

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REFERENCES
- Borrè E. & Ortali V. (1972) - Il genere Candida, Rec. Progr. Med., **53,** 379-298.
- Gentles J .C. & La Touche C.J. (1969) - Yeasts as human and animal pathogens, pp. 107-182Vin Rose, A.H. & Harrison J.S. eds: The Yeasts, vol. 1, Academic Press, London.
- Nickerson V.J. (1953) - Reduction of inorganic substances by Yeasts. I: Extracellular reduction of sulphite by species of Candida. J. Inf. Dis., **93,** 43-56.
- Van Unden N. & Buckley H. (1970) - Genus Candida albicans. pp. 893-1087 in Lodder J. ed.: The Yeasts, a Taxonomic Study. North Holland, Amsterdam.

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PRESENTATION	Packaging	REF.
NICKERSON CANDIDA AGAR WITH SWAB	**100 pcs**	**5260/SWAB**

The kit includes:
n. 100 Tubes (12x80 mm, with internal shaped conical bottom and screw cap, sterile) containing 3,5 mL of Biggy Agar (Nickerson);
n. 100 Swab (sterile, in single blister);
n. 100 Labels for a correct identification of the sample.

CND: W0104030399

SYMBOLS

 **Read the instructions**

 **Biological hazard**

CE **CE Mark (product complies with the requirements of Regulation (EU) 746/2017)**

 **Temperature limitation**

 **Use by**

IVD **For in vitro diagnostic use**

 **Manufacturer**