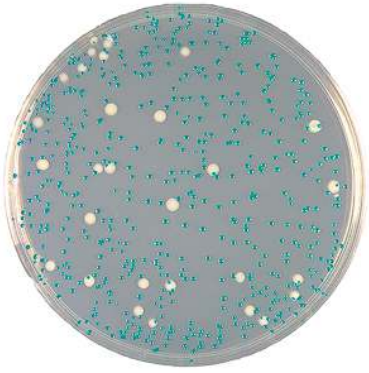
INSTRUCTIONS FOR USE

ChromArt

CHROMALBICANS AGAR

Ready-to-use plates



C.albicans (blue-green colonies)
and *C.tropicalis* (colourless colonies)

1-INTENDED USE

In vitro diagnostic device. Selective and chromogenic medium for the isolation of *Candida* spp. from clinical specimens and for the differentiation of *Candida albicans* and *Candida dubliniensis* from other species of *Candida* genus.

2 - COMPOSITION -TYPICAL FORMULA *

Growth factors	18.5 g
Chloramphenicol	0.05 g
Gentamicin	0.1 g
Tryptone	20 g
Glucose	1 g
Agar	13 g
Chromogenic substrate	0.1 g
Purified water	1000 mL

*The formula may be adjusted and/or supplemented to meet the required performances criteria.

3 - PRINCIPLE OF THE METHOD AND EXPLANATION OF THE PROCEDURE

Since the early 90s advances have been made in laboratory methods for diagnosis of *Candida* species, especially *Candida albicans*, resulting in more rapid and reliable identification.[1-3] One of these methods was the incorporation of chromogenic substrates directly into the growth agar media. A common principle among these media is the inclusion of a chromogenic substrate for β-hexosaminidase thus allowing the differentiation and presumptive identification of the most frequent and clinically important species, *C.albicans*.[4]
Chromalbicans Agar is a "first generation" chromogenic and selective medium for the isolation of *Candida* spp. from clinical specimens and the differentiation of *C.albicans-C.dubliniensis* group from other species of *Candida* genus. The selectivity of the medium is due to the presence of chloramphenicol and gentamicin which suppress the growth of bacteria. Differentiation is obtained by the presence of a single chromogenic compound for the detection of β-hexosaminidase enzymatic activity of *C.albicans* and *C.dubliniensis*. The hydrolysis of the compound results in the release of an insoluble blue-green chromophore that remains inside the colonies giving them a typical colour.

4 - PHYSICAL CHARACTERISTICS

Medium appearance	whitish, opalescent
Final pH at 20-25°C	6.2 ± 0.2

5 - MATERIALS PROVIDED - PACKAGING

Product	Type	REF	Pack
Chromalbicans Agar CND:W0104030202; EDMA:14.03.02.02; RDM: 1443951/R	Ready-to-use plates	548000	2 x 10 plates ø 90 mm primary packaging: 2 cellophane sachets secondary packaging: cardboard box

6 - MATERIALS REQUIRED BUT NOT PROVIDED

Sterile loops and swabs, incubator and laboratory equipment as required, ancillary culture media and reagents for the complete identification of the colonies.

7 - SPECIMENS

Chromalbicans agar is intended for the bacteriological processing of non-sterile clinical specimens such as mouth, throat, pharyngeal, vaginal swabs. Collect specimens before antimicrobial therapy where possible. Good laboratory practices for collection, transport and storage of clinical specimens should be applied.

8 - TEST PROCEDURE

Allow plates to come to room temperature and to dry the surface of the medium.
Inoculate by rolling the swab over a small area of the surface at the edge; then streak from this inoculated area to obtain well isolated colonies.
Incubate inoculated plates in aerobic conditions at 35-37°C for 18-24 or 48 hours.

9 - READING AND INTERPRETATION

After incubation, observe the bacterial growth and record the specific morphological and chromatic characteristics of isolated colonies.
C. albicans and *C.dubliniensis* grow with blue or blue-green colonies.
Other species of the genus *Candida* grow with colourless colonies.
Gram-positive and Gram-negative bacteria are almost inhibited.

10 - USER QUALITY CONTROL

All manufactured lots of the product are released for sale after the Quality Control has been performed to check the compliance with the specifications. However, it is responsibility of the end-user to perform Quality Control testing in accordance with the local applicable regulations, in compliance with accreditation requirements and the experience of the Laboratory. Here below are listed some test strains useful for the quality control.

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CONTROL STRAINS			INCUBATION T°/ T / ATM	EXPECTED RESULTS
C.albicans	ATCC	10231	35-37°C /18- 24h / A	good growth, blue-green colonies
C.tropicalis	NCPF	8841	35-37°C /18- 24h / A	good growth, colourless colonies
P.mirabilis	ATCC	10005	35-37°C /18- 24h / A	inhibited
P.aeruginosa	ATCC	27853	35-37°C /18- 24h / A	partially inhibited

A: aerobic incubation; ATCC is a trademark of American Type Culture Collection; NCPF: Public Health England, National Collection of Pathogenic Fungi.

11 - PERFORMANCES CHARACTERISTICS

The performance characteristics of Chromalbicans Agar was evaluated by Carillo-Munoz et al.[5] with 723 clinical isolates and type culture collection strains from different genera including *Candida, Cryptococcus, Pichia, Rhodotorula, Saccharomyces, Trichosporon* and *Zygosaccharomyces*. Presumptive identification was confirmed by germ tube test and carbohydrate assimilation on API-ATB ID 32C. Growth on Chromalbicans Agar was very useful for the presumptive identification of *C.albicans/C.dubliniensis* isolates, and sensitivity and specificity values were significantly high (>97%), since a very low number of isolates were found to be false negative or false positive. Sensitivity of *C.albicans/C.dubliniensis* detection: 97.09%; specificity *of C.albicans/C.dubliniensis* detection: 97.63%.
Predictive value of the negative result: 97.38%; predictive value of the positive result: 97.37%

Prior to release for sale, a representative sample of all lots of ready-to-use plates of Chromalbicans Agar and of the raw material used for the production of prepared plates (dehydrated Chromalbicans Agar REF 408000) are tested for productivity, specificity and selectivity by comparing the results with a previously approved Reference Batch.
Productivity and specificity are evaluated by semi-quantitative ecometric technique with the following strains: *C.albicans* ATCC 10231, *C.albicans* ATCC 18804, *C.albicans* ATCC 2091, *C.tropicalis* NCPF 8841. After incubation at 35-37°C for 18-24 hours, the amount of growth and the chromatic characteristics of the colonies are evaluated and recorded. *C.albicans* strains show a good grow with blue-green colonies while *C.tropicalis* grows with colourless colonies.
Selectivity is evaluated with modified Miles-Misra surface drop method by inoculating the plates with suitable decimal dilutions in saline of a 0.5 McFarland suspension of the non-target strains *P.aeruginosa* ATCC 27853, *E.faecalis* ATCC 19433, *P.mirabilis* ATCC 10005.
P.aeruginosa is partially inhibited and the growth of other non-target strains is totally inhibited.

12 - LIMITATIONS OF THE METHOD

- *C.dubliniensis* is ß-hexosaminidase positive and grows with blue-green colonies and therefore it is not differentiable from *C.albicans*.
- The medium contains a single chromogenic substrate for the detection of ß-hexosaminidase positive strains (*C.albicans* and *C.dubliniensis*) and therefore doesn't allow the differentiation between other species of the genus *Candida* which grow with colourless colonies.
- Even if the microbial colonies on the plates are differentiated on the basis of their morphological and chromatic characteristics, it is recommended that biochemical, immunological, molecular, or mass spectrometry testing be performed on isolates, from pure culture, for complete identification. If relevant, perform antimicrobial susceptibility testing.
- This culture medium is intended as an aid in the diagnosis of infectious diseases; the interpretation of the results must be made considering the patient's clinical history, the origin of the sample and the results of other diagnostic tests.

13 - PRECAUTIONS AND WARNINGS

- This product is a qualitative *in vitro* diagnostic, for professional use only; it is to be used by adequately trained and qualified laboratory personnel, observing approved biohazard precautions and aseptic techniques.
- This product is not classified as dangerous according to current European legislation.
- This culture medium contains raw materials of animal origin. The *ante* and *post mortem* controls of the animals and those during the production and distribution cycle of the raw materials, cannot completely guarantee that these products do not contain any transmissible pathogen. Therefore, it is recommended that the ready-to-use plates be treated as potentially infectious, and handled observing the usual specific precautions: do not ingest, inhale, or allow to come into contact with skin, eyes, mucous membranes. Download the TSE Statement from the website www.biolifeitaliana.it, describing the measures implemented by Biolife Italiana for the risk reduction linked to infectious animal diseases.
- All laboratory specimens should be considered infectious.
- The laboratory area must be controlled to avoid contaminants such as culture medium or microbial agents.
- Each plate of this culture medium is for single use only.
- Ready-to-use plates are not to be considered a "sterile product" as they are not subject to terminal sterilization but a product with controlled bio contamination, within the limits of defined specifications reported on the Quality Control Certificate.
- Sterilize all biohazard waste before disposal. Dispose the unused medium and the plates inoculated with samples or microbial strains in accordance with current local legislation.
- The Certificates of Analysis and the Safety Data Sheet are available on the website www.biolifeitaliana.it.
- The information provided in this document has been defined to the best of our knowledge and ability and represents a guideline for the proper use of the product but without obligation or liability. In all cases existing local laws, regulations and standard procedures must be observed for the examination of samples collected from human and animal organic districts, for environmental samples and for products intended for human or animal consumption. Our information does not relieve our customers from their responsibility for checking the suitability of our product for the intended purpose.

14 - STORAGE CONDITIONS AND SHELF LIFE

Upon receipt, store plates in their original pack at 2-8°C away from direct light. If properly stored, the plates may be used up to the expiration date. Do not use the plates beyond this date. Plates from opened plastic sachet can be used for 7 days when stored in a clean area at 2-8°C. Do not use the plates if the plastic sachet is damaged or if the dish is broken. Do not use the plates with signs of deterioration (e.g. microbial contamination, dehydration, shrinking or cracking of the medium, atypical colour, excess of moisture).

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15 - REFERENCES

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2. Perry JL, Miller GR. Umbelliferyl-labeled galactosaminide as an aid in identification of Candida albicans J Clin Microbiol 1987;25:2424-5.
3. Willinger BW, Manafi M, Rotter ML. Comparison of rapid methods using fluorogenic-chromogenic assays for detecting Candida albicans. Letters App Microbiol 1994; 18:47-49
4. Perry JD Freydie AM. The application of chromogenic media in clinical microbiology. J App Microbiol 2007; 103:2046
5. Carrillo-Muñoz AJ, Quindós G, Cárdenes CD, Alonso-Vargas R, Arévalo P, Brió S, Madariaga L. Evaluation of Chromalbicans Agar for presumptive identification of Candida albicans. Rev Iberoam Micol 2001; 18:105-8.

TABLE OF APPLICABLE SYMBOLS

REF or REF Catalogue number	LOT Batch code	IVD *In vitro* Diagnostic Medical Device	Manufacturer	Use by
Temperature limitation	Contents sufficient for <n> tests	Consult Instructions for Use	For single use only	Fragile, handle with care

REVISION HISTORY

Version	Description of changes	Date
Instructions for Use (IFU) - Revision 2	Updated layout and content in compliance with IVDR 2017/746	2020/10

Note: minor typographical, grammatical, and formatting changes are not included in the revision history.

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