

Instructions for Use

Colorex™ Candida Plus

Pre-Poured Media

REF - PP3018

1. Intended Use

For *in vitro* diagnostic use. PP3018 Colorex™ Candida Plus is a selective chromogenic culture medium intended for use in the qualitative detection, differentiation, and presumptive identification of *Candida* species, including *Candida auris*, from clinical specimens.

2. Composition*

<u>Ingredient</u>	<u>g/L</u>
Peptones	11.0
Chromogenic and selective mix	24.9
Agar	15.0

*Adjusted/supplemented as needed to meet performance requirements

3. Summary and Explanation

Candida are yeast species involved in various infections called candidiasis which can affect skin, respiratory tract, gastrointestinal tract (including the mouth), urogenital systems and blood. Candidiasis can be severe with significant morbidity for nosocomial infections or in immunocompromised patients. Although *C. albicans* is still the main species involved, other species such as *C. tropicalis*, *C. krusei*, *C. glabrata* and, more recently, *C. auris* have become increasingly common.

Candida auris is an emerging fungal pathogen that has been identified worldwide and is considered by the World Health Organisation as a critical priority pathogen ⁽¹⁾. PP3018 Colorex™ Candida Plus (manufactured by E&O under license from CHROMagar) appears to be promising in the identification and differentiation of *C. auris* from other *Candida* species ⁽¹⁾.

4. Principle

Peptones provide the required nitrogen, carbon, and vitamins. The chromogenic and selective mix is a proprietary additive rendering the agar selective for *Candida* spp. and allows for detection of specific enzyme activity that leads to the formation of coloured colonies and presumptive identification of colonies (see Section 9).

5. Physical Characteristics

	Medium
Appearance and Colour	Pale peach/straw firm gel
pH	6.1 ± 0.2

6. Materials Provided

PP3018 Colorex™ Candida Plus is supplied in packs of 10 x 90mm P090 Petri dishes (18-22ml fill) (product code: PP3018-P090). Each plate is ink-jet printed with (abbreviated) product name, product code, lot number and expiry date.

7. Materials Needed but not Provided

Standard microbiological laboratory materials e.g. sterile loops or swabs, collection containers, incubators, and quality control organisms.

8. Specimens

PP3018 Colorex™ Candida Plus is suitable for the testing of the following specimens:

- Clinical Specimens: Swabs from skin, throat, ears, vagina as well as sputum, urine and stools samples.

Sampling and transport equipment must be used in accordance with the end user's suppliers' recommendations. Refer to appropriate standard method or local guidance on sample collection and subsequent processing.

9. Test Procedures and Interpretation of results

PP3018 Colorex™ Candida Plus should be inoculated in parallel with Sabouraud agar, such as E&O PP0240 Sabouraud Dextrose Agar. Inoculate specimen directly onto the medium and streak across the agar surface using a sterile swab, loop or automated plate streaker.

Inoculated plates should be incubated at 30-37°C aerobically for 24-48 hours.

Identify presumptive positive isolates by examining any growth for coloured colonies (See table below).

<u>Microorganism</u>	<u>Typical colony appearance</u>
<i>C. albicans</i>	→ Green-blue
<i>C. auris</i>	→ Light blue with blue halo, blue from reverse side of the plate
<i>C. tropicalis</i>	→ Metallic blue with pink halo
<i>C. krusei</i>	→ Pink and fuzzy
<i>C. glabrata</i>	→ Mauve
Bacteria	→ Mostly inhibited

Perform further biochemical, serological, molecular, or mass spectroscopy analysis and antibiotic sensitivity testing to confirm identity of presumptive positive isolates. Tests can be done directly on colonies picked from the Colorex™ Candida Plus plates. Refer to relevant local guidelines.

10. Quality Control

Organism	Incubation	Result (Specificity)
<i>C. albicans</i> (NCPF 3179)	37 ± 1°C aerobically for 44 ± 4 hours	Growth: Green colonies
<i>C. glabrata</i> (NCPF 3309)	37 ± 1°C aerobically for 44 ± 4 hours	Growth: Pink colonies
<i>C. tropicalis</i> (NCPF 3290)	37 ± 1°C aerobically for 44 ± 4 hours	Growth: Metallic blue colonies with pink halo
<i>C. auris</i> (NCPF 8971)	37 ± 1°C aerobically for 44 ± 4 hours	Growth: Light blue colonies with blue halo
<i>E. coli</i> (NCTC 12241)	37 ± 1°C aerobically for 44 ± 4 hours	Inhibited

It is the responsibility of the user to perform Quality Control testing taking into consideration the intended use of the medium and in agreement with any local relevant guidelines (e.g., frequency, strains used, atmosphere, incubation temperature).

11. Performance

Colorex™ is a trademark of CHROMagar. Scientific publications regarding the performance of Colorex™ Candida Plus in clinical studies can be found at: <https://www.chromagar.com/en/product/chromagar-candida-plus/>

	Analytical data *	Clinical data **
Sensitivity	100%	100%
Specificity	100%	100%

Percentages calculated for *C. albicans*, *C. tropicalis*, *C. krusei* and *C. auris*.

* Data obtained after a 48 hours incubation at 37°C in aerobic conditions ⁽²⁾

** Data obtained after a 24-48 hours incubation at 37°C in aerobic conditions with 364 patients surveillance samples and 212 environmental samples ⁽³⁾

12. Limitations of the Media

- Biochemical or mass spectrometry testing using pure cultures may be necessary for complete identification; these tests may be done directly on colonies picked from the Colorex Candida Plus plates.
- Due to natural variation, some strains may grow poorly on this medium.

13. Precautions and Warnings

This product is considered non-hazardous under CLP regulations. Wear such PPE as recommended by laboratory COSHH assessment. During and after use, always handle all materials in a manner conforming to Good Laboratory Practices and consider that material under test should be regarded as a potential biohazard if mishandled.

Refer to E&O Poured Plate Material Safety Data Sheet.

14. Storage conditions and Shelf life

Store PP3018 in the original packaging between 2 and 8°C in the dark. Kept under these conditions it may be used up to date of expiry shown on product label.

Dispose of in accordance with local and national authority requirements. Do not use media if it is contaminated, discoloured, out of date, cracked or a precipitate is present. Additionally, do not use media if it has been stored inappropriately or the packaging has been damaged.

15. References

1. UKHSA (2023). *Candida auris*: a review of recent literature. Published on-line 14/06/2023. <https://www.gov.uk/government/consultations/candida-auris-update-to-management-guidance/candida-auris-a-review-of-recent-literature>
2. Bayona, J., García, C., Palop, N. and Cardona C. (2020) Evaluation of a novel chromogenic medium for *Candida* spp. identification and comparison with CHROMagar™ *Candida* for the detection of *Candida auris* in surveillance samples. *Diagnostic microbiology and infectious disease*, 98(4), pp.115168-115168.

3. Bayona, J., García, C., Palop, N., Martín, V., Padrón, C., Rodríguez, J., Pemán, J. and Cardona, C. (2022) Novel chromogenic medium CHROMagar™ Candida Plus for detection of Candida auris and other Candida species from surveillance and environmental samples: A multicenter study. Journal of Fungi, 8(3), pp.281.

Version History*

- 001 27/06/2023 - New document created
- 002 22/12/2025 - Typographical, grammatical, and formatting changes for increased clarity in line with updated product device file. Removed "direct" from Section 1.

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





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TABLE OF APPLICABLE SYMBOLS		IFU/PP3018 REV. 002			
REF o REF Catalogue number	LOT Batch code	IVD <i>In vitro</i> Diagnostic Medical Device	 Manufacturer	 Use by	
 Temperature limitation	 Contents sufficient for <n> tests	 Consult Instructions for Use	 Keep away from direct light	 Store in a dry place	