

Instructions for Use

REF - PP3010

Colorex™ Candida

Pre-Poured Media

1. Intended Use

For *in vitro* diagnostic use only. PP3010 Colorex™ Candida is a selective chromogenic culture medium intended for use in the qualitative detection, differentiation and presumptive identification of *Candida* species from clinical specimens.

2. Composition*

Ingredient	g/L
Peptones	10.2
Chromogenic mix	22.0
Agar	15.0
Chloramphenicol	0.5

*Adjusted/supplemented as needed to meet performance requirements

3. Summary and Explanation

Candida species are yeasts involved in various infections called candidiasis, which can affect damaged skin, the respiratory tract, digestive and urogenital systems. Candidiasis can be severe with significant morbidity associated with hospital acquired infections or in immunocompromised patients. Although *C. albicans* is still the prevalent pathogenic species, the increased use of antifungal agents has led to an increase in infections due to other species such as *C. tropicalis*, *C. krusei* and *C. glabrata*. In 2016, the World Health Organization added *C. auris* to this list, with over 90% of isolates resistant to fluconazole. In addition, some *C. auris* strains are multidrug resistant to amphotericin B, voriconazole, and/or echinocandins.

In recent years, there has been an increase in the number of immuno-compromised patients, which has in turn led to an increased rate of infections associated with *Candida* species. There were 2151 reported cases of candidaemia in 2016 with *C. albicans* accounting for 42%, *C. glabrata* for 25%, *C. parapsilosis* for 9% and *C. tropicalis* for 3% of infections in England, Wales, and Northern Ireland ⁽¹⁾.

4. Principle

Colorex™ Candida incorporates chromogenic substrates to allow for the recognition of a mixed *Candida* spp. population within a clinical specimen, as well as the pre-dominant species, thereby allowing for a patient specific treatment plan at the earliest possible opportunity. Most bacterial species will be inhibited due to the inclusion of chloramphenicol as a selective agent.

5. Physical Characteristics

	Medium
Appearance and Colour	Straw firm gel
pH	6.1 ± 0.2

6. Materials Provided

PP3010 Colorex™ Candida is supplied in packs of 10 x 90 mm PP090 Petri dishes (18-22ml fill); 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

PP3010 Colorex™ Candida is suitable for the testing of the following specimens:

- Clinical: Skin, ear and throat swabs, sputum samples, urine, stool or faecal swabs and vaginal swabs

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

9. Test Procedures and Interpretation of results

Allow the plates to come to room temperature.

Inoculate specimen directly onto the medium and streak across the agar surface using a sterile loop or automated plate streaker. Inoculated should be incubated at 35-37°C aerobically for 20-48 hours.

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

Organism	Expected colour
<i>C. albicans</i> →	Green
<i>C. tropicalis</i> →	Metallic blue
<i>C. krusei</i> →	Pink, fuzzy
<i>C. kefyr</i> , <i>C. glabrata</i> →	Mauve to brown
Other species →	White to mauve

Perform further biochemical or mass spectroscopy testing to confirm identity of presumptive positive isolates. Refer to relevant local guidelines.

10. Quality Control

Organism	Incubation	Result (Specificity)
<i>C. albicans</i> (NCPF 3179)	37 ± 1°C aerobically for 48 hours	Growth: Green colonies
<i>C. glabrata</i> (NCPF 3309)	37 ± 1°C aerobically for 48 hours	Growth: Pink colonies
<i>C. tropicalis</i> (NCPF 3290)	37 ± 1°C aerobically for 48 hours	Growth: Blue colonies
<i>E. coli</i> (NCTC 12241)	37 ± 1°C aerobically for 48 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 the Candida medium with clinical specimens can be found at <https://www.chromagar.com/en/product/chromagar-candida>

	Analytical data *	Clinical data **
	Sensitivity & Specificity	Colorex™ Candida Sensitivity & Specificity
<i>C. albicans</i>	100%	96.6% / 97.9%
<i>C. tropicalis</i>	97.9% / 98.8%	100% / 98.5%
<i>C. krusei</i>	100%	-
<i>C. glabrata</i>	97.7 % / 98.4 %	100%

* Data obtained after a 48-hour incubation at 37°C aerobically ⁽²⁾

** Data obtained after a 24–48-hour incubation at 37°C aerobically with 364 patients surveillance samples and 212 environmental samples ⁽³⁾

12. Limitations of the Medium

- Definitive identification requires additional testing of isolates (e.g., biochemical tests, MALDI-TOF).
- Candida glabrata* and *C. parapsilosis* cannot be readily distinguished on this medium.
- Candida dubliniensis* will form dark green colonies on Colorex™ Candida so additional testing is required to confirm presence in the specimen to avoid confusion with *C. albicans*.
- Candida auris* isolates will grow on this medium but the colony colour may vary from white to pale purple/pink so further testing will be required to confirm identification.

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 PP3010 Colorex™ Candida in the original packaging between 2 - 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 medium if it is contaminated, discoloured, out of date or if cracks in the agar medium are present. Additionally, do not use medium if it has been stored inappropriately or the packaging has been damaged.

15. References

- Laboratory surveillance of candidemia in England, Wales and Northern Ireland. 2016. Health Protection Report Volume 11 Number 32.
- Mulet Bayona, J., Salvador García, C., Tormo Palop, N. and Gimeno 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. Diagn Microbiol Infect Dis, 98(4), 115168.

3. Mulet Bayona, J., Salvador García, C., Tormo Palop, N., Valentín Martín, A., González Padrón, C., Colomina Rodríguez, J., Pemán, J. and Gimeno 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. J Fungi (Basel), 8(3), 281.

Version History*

- 001 08/02/23 - New Document Created
- 002 14/11/23 - Add *E. coli* NCTC 12241 as negative control
- 003 09/12/2025 - Typographical, grammatical, and formatting changes for increased clarity in line with updated product device file.

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TABLE OF APPLICABLE SYMBOLS

IFU/PP3010 REV. 003

 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	 Keep away from direct light	 Store in a dry place