SUMMARY AND EXPLANATION

chromID™ Candida agar is a medium for:
• the selective isolation of yeasts,
• the identification of the species *C. albicans*,
• the presumptive differentiation of a group of species comprising *C. tropicalis*, *C. lusitaniae* and *C. kefyr* (1, 2, 3, 4, 5).

PRINCIPLE

The specific hydrolysis of a hexosaminidase chromogenic substrate in the presence of an inducer of the enzyme (bioMérieux patent) causes the *C. albicans* colonies to turn blue.

The possible hydrolysis of a second substrate differentiates mixed cultures and orients identification of other species. Colonies which hydrolyze this substrate are pink (bioMérieux patent).

The inhibition mixture inhibits the growth of most bacteria.

CONTENT OF THE KIT

| REF 43 631 | Pack of 2 x 10 plates (90 mm) |
| REF 43 639 | Pack of 10 x 10 plates (90 mm) |

* printed on each plate

COMPOSITION

**Theoretical formula**

This medium can be adjusted and/or supplemented according to the performance criteria required:

- Yeast extract .............................................................. 6 g
- Malt extract .............................................................. 4.5 g
- Enzyme substrates and regulators .................................. 1.71 g
- Agar ........................................................................... 14 g
- Antibiotic mixture ....................................................... 0.107 g
- Purified water ................................................................ 1 l
- pH 6.7

MATERIAL REQUIRED BUT NOT PROVIDED

• Bacteriology incubator.

WARNINGS AND PRECAUTIONS

• For *in vitro* diagnostic use only.
• For professional use only.
• All specimens, microbial cultures and inoculated products should be considered infectious and handled appropriately. Aseptic technique and usual precautions for handling the microbial group studied should be observed throughout this procedure. Refer to "CLSI® M29-A, Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline - Current Revision". For further information on handling precautions, refer to "Biosafety in Microbiological and Biomedical Laboratories – CDC/NIH – Latest edition", or the current regulations in the country of use.
• Culture media should not be used as manufacturing material or components.
• Do not expose the medium to light.
• Do not use reagents after the expiry date.
• Do not use reagents if the packaging is damaged.
• Do not use contaminated plates, or plates that exude moisture.
• Interpretation of the test results should be made taking into consideration the patient's history, the source of the specimen, colonial and microscopic morphology and, if necessary, the results of any other tests performed.
• Use of the medium may be difficult for people who have problems recognizing colors.
• The performance data were obtained using the procedure indicated in this package insert. Any change or modification in the procedure may affect the results.

STORAGE CONDITIONS

• Store the plates in their box at 2–8°C until the expiry date.
• If not in the box, plates can be stored in the cellophane sachet for 2 weeks at 2–8°C in the dark.

SPECIMENS

All types of specimens may be used and should be inoculated directly onto the agar.

Good laboratory practices for collection and transport should be respected and adapted to the type of specimen.

INSTRUCTIONS FOR USE

This medium must not be exposed to light other than during the inoculation and reading steps.

1. Allow plates to come to room temperature in the dark.
2. Inoculate the specimen.
3. Immediately incubate the plates inverted (agar-side up) at 37°C in aerobic conditions and in the dark. The user is responsible for choosing the appropriate temperature for the intended use, in accordance with current standards.

The cultures are generally examined after 24, 48 hours of incubation, or even 72 hours depending on the type of specimen and the kind of microorganism being detected.

READING AND INTERPRETATION

After incubation, observe the color of the colonies:
• Pale blue to dark blue: characteristic of *Candida albicans*.
• Pink: characteristic of *Candida tropicalis*, *Candida lusitaniae* and *Candida kefyr*.

Identification of the microorganism isolated must be followed by biochemical and/or immunological tests.
• Creamy-white: no predictive value

Identification of the microorganism isolated must be followed by biochemical and/or immunological tests.

Observe colony morphology:
• Take into account the characteristic appearance of filamentous fungi and *Candida krusei* (7).
QUALITY CONTROL

Protocol:
The nutrient capacity of the medium can be tested using the following strains:
- Candida albicans ATCC® 10231
- Candida tropicalis ATCC® 9968

Range of expected results:

<table>
<thead>
<tr>
<th>Strain</th>
<th>Results at 33-37°C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Candida albicans</td>
<td>Growth within 48 hours</td>
</tr>
<tr>
<td>ATCC® 10231</td>
<td></td>
</tr>
<tr>
<td>Candida tropicalis</td>
<td>Growth within 48 hours</td>
</tr>
<tr>
<td>ATCC® 9968</td>
<td></td>
</tr>
</tbody>
</table>

Note:
It is the responsibility of the user to perform Quality Control taking into consideration the intended use of the medium, and in accordance with any local applicable regulations (frequency, number of strains, incubation temperature, etc.).

LIMITATIONS OF THE METHOD
- chromID™ Candida agar does not enable C. albicans to be distinguished from C. dubliniensis. For this species, which is phenotypically very similar to C. albicans, the color is often weaker and occurs later (after 48 hours of incubation) (2).
- Some Trichosporon colonies may be blue to blue-green. This genus can be distinguished from Candida by the morphological appearance of the colonies (4).
- Certain species other than the expected ones (e.g. Candida guilliermondii, Candida norvegensis, Candida pulcherma and Cryptococcus neoformans) may produce more or less dark pink colors (2, 4).
- A few strains of Candida tropicalis and Pichia ohmeri may produce a blue color. (6).
- Certain strains of Candida tropicalis, Candida lusitaniae and Candida kefyr do not systematically produce pink colonies, particularly after 24 hours. Therefore, the presence of white colonies does not rule out these species.
- Growth depends on the requirements of each individual microorganism. It is therefore possible that certain yeast strains which have specific requirements (substrate, temperature, etc.) may not grow or may not produce color.
- If the instructions for use are not complied with (exposure to light), a lack of color for yeast colonies, or even inhibited growth of certain strains may be observed.
- Dispose of non inoculated plates if they have been exposed to light.
- Depending on the specimens analyzed and the microorganisms being tested for, it is recommended to use chromID™ Candida agar in conjunction with non-selective media (e.g. Sabouraud Agar).
- Some very rare bacterial species which are resistant to the antibiotics in the medium, may produce blue colonies which can be differentiated from C. albicans by their morphological appearance.

PERFORMANCE
Performance was evaluated at 35–37°C using 500 human specimens of various origins (respiratory, urinary, stools etc.).

chromID™ Candida (CAN2) was compared to Candida ID (CAND).

Nutrient capacity:
178 specimens produced positive cultures after 48 hours (growth of yeasts or molds) on at least one of the two media. The distribution of the isolated fungi (yeasts and/or molds) is as follows:

<table>
<thead>
<tr>
<th></th>
<th>chromID™ Candida</th>
<th>Candida ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>24 hours</td>
<td>124</td>
<td>123</td>
</tr>
<tr>
<td>48 hours</td>
<td>211</td>
<td>203</td>
</tr>
</tbody>
</table>

Identification of C. albicans
The distribution of the specimens which produced blue colonies is as follows:

<table>
<thead>
<tr>
<th></th>
<th>chromID™ Candida</th>
<th>Candida ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>C. albicans</td>
<td>73</td>
<td>74</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>83%</td>
<td>85%</td>
</tr>
<tr>
<td>PPV</td>
<td>99%</td>
<td>99%</td>
</tr>
</tbody>
</table>

C. albicans = Number of strains identified as Candida albicans
PPV = Positive Predictive Value

Differentiation of C. tropicalis, C. lusitaniae and C. kefyr
The distribution of the specimens which produced pink colonies is as follows:

<table>
<thead>
<tr>
<th></th>
<th>chromID™ Candida</th>
<th>Candida ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>24 hours</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>48 hours</td>
<td>18</td>
<td>18</td>
</tr>
</tbody>
</table>

Selectivity
The distribution of the 500 specimens which showed bacterial growth is as follows:

<table>
<thead>
<tr>
<th></th>
<th>chromID™ Candida</th>
<th>Candida ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>24 hours</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>48 hours</td>
<td>2</td>
<td>23</td>
</tr>
</tbody>
</table>

WASTE DISPOSAL
Unused reagents may be considered as non hazardous waste and disposed of accordingly.
Dispose of used reagents as well as any other contaminated disposable materials following procedures for infectious or potentially infectious products.
It is the responsibility of each laboratory to handle waste and effluents produced according to their nature and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations.
LITERATURE REFERENCES


INDEX OF SYMBOLS

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>REF</td>
<td>Catalogue number</td>
</tr>
<tr>
<td>IVD</td>
<td>In Vitro Diagnostic Medical Device</td>
</tr>
<tr>
<td>‡</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>‡</td>
<td>Temperature limitation</td>
</tr>
<tr>
<td>‡</td>
<td>Use by</td>
</tr>
<tr>
<td>LOT</td>
<td>Batch code</td>
</tr>
<tr>
<td>‡</td>
<td>Consult Instructions for Use</td>
</tr>
<tr>
<td>‡</td>
<td>Protect from light</td>
</tr>
<tr>
<td>‡</td>
<td>∑ Contains sufficient for &lt;n&gt; tests</td>
</tr>
</tbody>
</table>

WARRANTY

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