

HiCandida™ Identification Kit

KB006

Intended use

KB006 is a standardized test system that can be used for identification and differentiation of *Candida* species from clinical specimen and non clinical samples using pure isolate.

Kit contents

1. Each kit contains 5/10/20 kits of KB006, sufficient material to perform 5/10/20 tests. Kit contains sterile media for Urease production and 11 different carbohydrates utilization tests - Melibiose, Lactose, Maltose, Sucrose, Galactose, Cellobiose, Inositol, Xylose, Dulcitol, Raffinose, Trehalose
2. Technical product insert.
3. Result Interpretation Chart and Result Entry Datasheet.
4. Identification Index.

Material Required but not supplied :

1. McFarland standard
2. Inoculation loops, pipettes
3. Enrichment medium / Isolation media

Direction

Preparation of inoculum :

- KB006 cannot be used directly on clinical specimens. The organisms to be identified have to be first isolated and purified. Only pure cultures should be used.
- Isolate the organism to be identified on a common medium like Sabouraud Dextrose Agar (M063) or Potato dextrose Agar (M096).
- Prepare the inoculum by picking 2- 4 well isolated colonies and make a homogeneous suspension in 2-3ml sterile saline. The density of the suspension should be adjusted to 0.5 OD at 620 nm.
- Alternatively, inoculum can be prepared by inoculating a single isolated colony in 5ml Potato Dextrose Broth, Granulated (GM403) and incubating at 22°C -25°C for 6 - 8 hours till the inoculum turbidity is 0.5 OD at 620nm.

Inoculation of the kit :

1. Open the kit aseptically. Peel off the sealing foil.
2. Inoculate each well with 50 µl of the above inoculum by surface inoculation method.
3. Alternatively, the kit can also be inoculated by stabbing each individual well with a loopful of inoculum.

Incubation :

Temperature of incubation: 22.5°C ± 2.5°C.

Duration of incubation: 24-48 hours.

Interpretation of results :

Interpret results as per the standards given in the identification index after the end of incubation period that is after 24 - 48 hours.

Principle

Each KB006 kit is a standardized colorimetric identification system utilizing twelve conventional biochemical tests. The tests are based on the principle of pH change and substrate utilization. On incubation, organisms undergo metabolic changes which are indicated by a spontaneous colour change in the media.

Type of specimen

Pure isolate from clinical specimen and non clinical sample

Specimen collection and handling

Refer direction

Warning and Precautions

In Vitro diagnostic Use. For professional use only. Read the label before opening the pack. Wear protective gloves/protective clothing/eye protection/ face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling clinical specimens. Aseptic conditions should be maintained during inoculation and handling of the kits. Reagents should not come in contact with skin, eyes or clothing. Safety guidelines may be referred in individual safety data sheets.

Limitations

1. Allow the reagents to come to room temperature after removal from the refrigerator .
2. In case of carbohydrate fermentation test some microorganisms show weak reaction. In this case record the reaction as \pm and incubate further upto 48 hours. Orange colour after 48 hours of incubation should be interpreted as a negative reaction.
3. At times organisms give conflicting result because of mutation or the media used for isolation, cultivation and maintenance.
4. The identification index has been compiled from standard references and results of tests carried out in the laboratory.
5. Erroneous false negative results may be obtained if the inoculum turbidity is less than 0.5 OD.
6. Results are more prominent if an enriched culture is used instead of a suspension.
7. It cannot be used directly for clinical specimens. The microorganisms to be identified have to be first isolated on appropriate isolation media. Only pure cultures should be used.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance

Sterile white opaque strip with 12 wells containing media for Urease production and 11 different carbohydrates utilization tests - Melibiose, Lactose, Maltose, Sucrose, Galactose, Cellobiose, Inositol, Xylose, Dulcitol, Raffinose, Trehalose

Quantity of medium

0.8 ml of medium in each well.

Sterility Check

Passes release criteria

Interpretation of results :

Interpret results as per the standards given in the identification index after the end of incubation period that is after 24 - 48 hours.

1. Urease test : Well No. 1

- Change of colour from orangish yellow to pink colour indicates positive reaction.
- No colour change indicates a negative reaction.

2. Carbohydrate fermentation Test : Well No. 2-12

- Positive test is indicated by a colour change to yellow colour.
- Red or no colour change indicates a negative reaction.

Result Interpretation Chart

Well No.	Test	Principle	Original Colour of the medium	Positive Reaction	Negative reaction
1	Urease	Detects Urease enzyme	Orangish yellow	Pink	Orangish yellow
2	Melibiose	Melibiose utilization	Pinkish Red / Red	Yellow	Red / Pink
3	Lactose	Lactose utilization	Pinkish Red / Red	Yellow	Red / Pink
4	Maltose	Maltose utilization	Pinkish Red / Red	Yellow	Red / Pink
5	Sucrose	Sucrose utilization	Pinkish Red / Red	Yellow	Red / Pink
6	Galactose	Galactose utilization	Pinkish Red / Red	Yellow	Red / Pink
7	Cellobiose	Cellobiose utilization	Pinkish Red / Red	Yellow	Red / Pink
8	Inositol	Inositol utilization	Pinkish Red / Red	Yellow	Red / Pink
9	Xylose	Xylose utilization	Pinkish Red / Red	Yellow	Red / Pink
10	Dulcitol	Dulcitol utilization	Pinkish Red / Red	Yellow	Red / Pink
11	Raffinose	Raffinose utilization	Pinkish Red / Red	Yellow	Red / Pink
12	Trehalose	Trehalose utilization	Pinkish Red / Red	Yellow	Red / Pink

Identification Index of various *Candida species*

Tests	Urease	Melibiose	Lactose	Maltose	Sucrose	Galactose	Cellobiose	Inositol	Xylose	Dulcitol	Raffinose	Trehalose
<i>Candida albicans</i>	-	-	-	+	+	+	-	-	+	-	-	+
<i>Candida catenulata</i>	-	-	-	+	-	+	-	-	+	-	-	-
<i>C. dubliniensis</i>	-	-	-	+	+	+	-	-	+	-	-	+
<i>C. famata</i>	-	+	+	+	+weak	+	+	-	+	+	+	+weak
<i>C. glabrata</i>	-	-	-	+	-	-	-	-	-	-	-	+
<i>C. guilliermondii</i>	-	+	-	+	+	+	+	-	+	+	+	+
<i>C. kefyr</i>	-	-	+	-	+	+	+	-	+	-	+	-
<i>C. krusei</i>	+	-	-	-	-	-	-	-	-	-	-	-
<i>C. lambi</i>	-	-	-	-	-	-	-	-	+	-	-	-
<i>C. lipolytica</i>	+	-	-	-	-	-	-	-	-	-	-	-
<i>C. lusitanae</i>	-	-	-	+	+	+	+	-	+	-	-	+
<i>C. parapsilosis</i>	-	-	-	+	+	-	-	-	+	-	-	-
<i>C. pintolopesii</i>	-	-	-	-	-	-	-	-	-	-	-	-
<i>C. rugosa</i>	-	-	-	-	-	+	-	-	+	-	-	-
<i>C. tropicalis</i>	-	-	-	+	+	+	+	-	+	-	-	+
<i>C. zeylanoides</i>	-	-	-	-	-	-	-	-	-	-	-	+
<i>C. pseudotropicalis</i>	-	-	+	-	+	+	+	-	+	Nd	+	-
<i>C. stellatoidea</i>	-	-	-	+	-	+	-	-	+	Nd	-	+

Note : Based on % strains showing reactions following symbols have been assigned from laboratory results and standard references.

+ = Positive reaction (more than 90 %) - = Negative reaction
 * = Strain variation. Nd = Not detected

Storage and Shelf Life

On receipt store between 2-8°C. Use before expiry date on the label. Product performance is best if used within stated expiry period.

Disposal

After use, kits and the instruments used for isolation and inoculation (pipettes, loops etc.) must be disinfected using a suitable disinfectant and then discarded by incineration or autoclaving in a disposal bag. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (2,3).

Reference

1. Bergey's Manual of Systematics of Archaea and Bacteria (BMSAB), 2015.
2. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.
3. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock, D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.

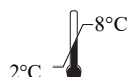
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**In vitro diagnostic
medical device**



Storage temperature



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**Do not use if
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Do not re-use

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