K70002 GT-7 GERM TUBE

INTENDED USE:
GT-7 is single use vial intended for the preliminary identification of *Candida albicans* by germ tube formation.

SUMMARY:
Candida albicans is the most frequently found yeast pathogen in clinical diagnosis.The rapid preliminary clinical identification of this yeast is usually based on the formation of hyphae by the yeast cell that are half its width, up to three or four times the length of the cell, and with no constriction seen between the cell and the hyphal growth. Known as a germ tube, this growth occurs when the yeast is incubated in a serum medium at 35-37 degrees C. The lyophilization stabilizes the serum so that it can be stored for long periods under refrigeration only making freezing unnecessary. The single use vial, sold in packages of 20, make it easy and affordable for every laboratory, regardless of size, to identify this yeast.

FORMULA:
The GT-7 tube contains pure lyophilized Fetal Bovine Serum in a single test quantity.

STORAGE AND SHELF LIFE:
Storage: Upon receipt store vials at 2-8 degrees C. The product may be shipped without refrigeration if transit time is less than one week. Product should not be used if there are any signs of deterioration, contamination, or if the expiration date has passed. The expiration date applies to the product in its intact packaging when stored as directed.

PRECAUTIONS:
For in vitro diagnostic use only. Observe approved biohazard precautions and aseptic techniques. To be used only by adequately trained and qualified laboratory personnel. Sterilize all biohazard waste before disposal.

PROCEDURE:
Specimen Collection: This product is not intended for primary isolation of patient specimens. GT-7 may be used as a rapid preliminary identification method, in conjunction with other biochemical and/or serological tests to identify cultures of isolated yeasts.
To Use: Label the vial then rehydrate with 7 drops (315 µl) of sterile water (it is not necessary to bring to room temperature). With a sterile loop, applicator stick, or pasteur pipette, inoculate the vial with the isolate, mixing well. Avoid heavy inoculum which may give false negative results. Incubate aerobically in an incubator, water bath, or heat block for three hours at 35-37 degrees C (37 degrees C is preferable). Examine culture for presence of germ tubes by placing one drop of media on a slide, covering it with a cover slip, and examining on high dry magnification (400X).

INTERPRETATION OF RESULTS:
A positive test is determined by the presence of a thin, tube-like structure which is half the width and approximately three to four times the length of the cell. No constriction should be seen at the germ tube/cell wall interface. The absence of the germ tube is a negative test.

LIMITATIONS:
C*andida dubliniensis* may also give a positive germ tube test. *Candida tropicalis* can also be interpreted as positive however blastoconida are larger, usually have a constriction at the origin of the germ tube, and less than 15% of cells are positive. GT-7 is a rapid presumptive method to detect the presence of *Candida albicans.* Additional biochemical or serological tests are required for final confirmation (see references below). **K9142 Candida Screen** provides 2 biochemical tests and is useful as a additional confirmation when combined with the GT-7. Water must be sterile and yeast isolate must be pure, as germ tube production may be inhibited or delayed in contaminated FBS.

MATERIALS REQUIRED BUT NOT PROVIDED:
Standard microbiological supplies and equipment such as sterile water, loops, other culture media, swabs, applicator sticks, incinerators, and incubators, etc., as well as serological and biochemical reagents, are not provided.

QUALITY CONTROL:
The following organisms are used for testing at KEY SCIENTIFIC:
Positive: germ tubes formed within 2 hours: Candida albicans ATCC®36232
Negative: no germ tubes formed within 2 hours Candida tropicalis ATCC® 750
End users may use any strain of known reactivity. Unused GT-7 should have a visible clump in the bottom of the tube. Upon rehydration, it should be clear, and medium amber in color.

REFERENCES:

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5. Koneman, E.W., et al. 1997. Color Atlas and Textbook of Diagnostic Microbiology, 5th ed. J.B. Lippincott Company, Philadelphia, PA.
6. Kwon-Chung, K.J. and J.E. Bennett. 1992. Medical Mycology. Lea and Febiger, Malvern, PA.
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