

remel

Germ Tube Solution

INTENDED USE

Remel Germ Tube Solution is recommended for use in qualitative procedures for germ tube production to aid in the identification of *Candida albicans*.

SUMMARY AND EXPLANATION

Germ tubes are short, tube-like structures produced by *C. albicans* when incubated at 35-37°C for 2-4 hours in pooled human serum. The use of human serum as a germ tube induction medium has raised questions about standardization, reproducibility, and safety. Various media, including fetal bovine serum, have been evaluated as substitutes for human serum in performing the germ tube test.¹⁻³

PRINCIPLE

Formation of germ tubes is associated with increased synthesis of protein and ribonucleic acid. Germ Tube Solution contains tryptic soy broth and fetal bovine serum, essential nutrients for protein synthesis. It is lyophilized for stability.

REAGENTS (CLASSICAL FORMULA):*

Tryptic Soy Broth..... 20.0 g
Fetal Bovine Sera..... Q.S.
Demineralized Water (CAS 7732-18-5) 1000.0 ml

*Adjusted as required to meet performance standards.

PRECAUTIONS

This product is for *In Vitro* diagnostic use and should be used by properly trained individuals. Precautions should be taken against the dangers of microbiological hazards by properly sterilizing specimens, containers, and media after use. Directions should be read and followed carefully.

STORAGE

Store lyophilized product in its original container at 2-8°C until used. Allow product to equilibrate to room temperature before use. Do not incubate prior to use.

PRODUCT DETERIORATION

This product should not be used if (1) there is evidence of contamination, (2) the expiration date has passed, or (3) there are other signs of deterioration.

SPECIMEN COLLECTION, STORAGE, TRANSPORT

Specimens should be collected and handled following recommended guidelines.⁴

MATERIALS REQUIRED BUT NOT SUPPLIED

(1) Loop sterilization device, (2) Inoculating loop, swabs, collection containers, (3) Incubators, alternative environmental systems, (4) Supplemental media, (5) Quality control organisms, (6) Test tubes, (7) Microscope slides, coverslips, (8) Disposable pipettes, (9) Sterile demineralized water.

PROCEDURE

1. Rehydrate Germ Tube Solution with sterile demineralized water according to the volume size indicated on the vial label.
2. Aliquot 0.5 ml of solution into clean test tubes, one tube for each test isolate and control. Unused Germ Tube Solution may be dispensed into tubes (0.5 ml each), capped tightly, and frozen at -20°C or below for up to 4 months.
3. Make a dilute suspension of the test isolate or control from a single colony. Touch the tip of a disposable pipette to the colony and emulsify in the solution. **DO NOT** inoculate the solution heavily; excessive inoculum causes a significant decrease in the percentage of cells forming germ tubes.⁵ Positive and negative controls should be tested simultaneously.
4. Incubate aerobically at 35-37°C for 2-4 hours.
5. Examine microscopically under high (40 X) magnification for the presence of germ tubes.

INTERPRETATION

Positive Test - A short hyphal (filamentous) extension arising laterally from a yeast cell, with no constriction at the point of origin

Negative Test - No hyphal (filamentous) extension arising from a yeast cell or a short hyphal extension constricted at the point of origin

QUALITY CONTROL

All lot numbers of Germ Tube Solution have been tested using the following quality control organisms and have been found to be acceptable. Testing of positive and negative controls should be performed in accordance with established laboratory procedures. If aberrant quality control results are noted, patient results should not be reported.

CONTROL	INCUBATION	RESULTS
<i>Candida albicans</i> ATCC® 10231	Aerobic, 2-4 h @ 35-37°C	Positive
<i>Candida glabrata</i> ATCC® 2001	Aerobic, 2-4 h @ 35-37°C	Negative

LIMITATIONS

1. The yeast formerly named *Candida stellatoidea* also produces germ tubes; however, it has been combined with *C. albicans* and no longer exists as a separate species.⁶
2. *Candida dubliniensis*, first described in 1995, also produces germ tubes and chlamydospores.⁷ Growth at elevated temperatures and colony morphology on differential media have been shown to facilitate differentiation of *C. albicans* and *C. dubliniensis*.⁸⁻⁹
3. *Candida tropicalis* may produce early pseudohyphae that can be confused with germ tubes; however, such hyphal extensions are constricted at the point of origin with the yeast cell in contrast to germ tubes.^{4,5}
4. This test is only part of the overall scheme for identification of yeasts. Further testing is required for definitive identification. Consult appropriate references for further instructions.^{4,5}

PERFORMANCE CHARACTERISTICS

In a comparative study, the performance of Germ Tube Solution and carbohydrate assimilation tests for identification of *C. albicans* were evaluated. The following results were obtained.^{10,11}

At 2 hours incubation:

Carbohydrate Assimilation	Remel Germ Tube Solution		
	Positive	Negative	Total
Positive	55	2	57
Negative	1	68	69
Total	56	70	126

Sensitivity = 96.6%

Specificity = 98.6%

Note: At 4 hours incubation, sensitivity increased to 100%.

In a comparative study between pooled human serum and Germ Tube Solution the following results were obtained.^{10,11}

At 2 hours incubation:

Pooled Human Serum	Remel Germ Tube Solution		
	Positive	Negative	Total
Positive	55	2	57
Negative	1	67	68
Total	56	69	125

Agreement = 97.6%

Note: At 4 hours incubation, agreement increased to 100%.




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PACKAGING

- REF R21066, Germ Tube Solution.....5 ml/Vial
- REF R21069, Germ Tube Solution.....6 X 5 ml/Pk
- REF R21068, Germ Tube Solution.....25 ml/Vial

Symbol Legend

REF	Catalog Number
IVD	In Vitro Diagnostic Medical Device
LAB	For Laboratory Use
	Consult Instructions for Use (IFU)
	Temperature Limitation (Storage Temp.)
LOT	Batch Code (Lot Number)
	Use By (Expiration Date)

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